FOREWORD

State and local immunization programs are critically important leaders in the nation's immunization system, which the Institute of Medicine has called a "national treasure." Success at the state and local level has translated directly into success at the national level. The important improvements to the health of children that you provide comes from procedures and systems you create at the state and local level. The structure of these procedures and systems is the subject of this Immunization Program Operations Manual.

This Immunization Program Operations Manual (IPOM) is an outgrowth of the Program Performance Guidelines released in draft by the National Immunization Program (NIP) in 1998 and 2000. This new format represents the formal separation of information about "What an effective immunization program looks like" from instructions on "How to write a grant proposal" which will remain in the annual Grant Guidance document. Although now separate, the two documents are essential companions to each other.

Crucial input for the IPOM was provided by a workgroup of the Association of Immunization Managers and the Program Operations Branch at NIP. Additional consultation was provided by subject matter experts from other parts of NIP. In developing the IPOM, these individuals were responsive to the Institute of Medicine "Calling The Shots: Immunization Finance Policies and Practices" that identified the roles of the nation's immunization system and made important recommendations to immunization program operations at the federal, state and local levels. These include the need for immunization policy to be national in scope while remaining flexible enough in implementation to be able to respond to special circumstances that occur at the state and local levels. The Institute of Medicine report also emphasized the important roles federal and state governments play in ensuring an adequate nationwide supply of vaccine.

The IPOM reflects a shift in NIP's approach toward state and local immunization programs that enables both program managers and NIP staff to focus on progress toward meaningful objectives rather than on meeting one-size-fits-all requirements. Previous guidelines on immunization program activities had focused on grant requirements and recommendations that did not consider the circumstances of individual programs. Since the IPOM can be updated as needed, this new approach will facilitate the rapid dissemination of up-to-date information about strategies and activities that work, packaged in a way immunization program manager will find useful when planning and implementing annual program activities.

We hope that the IPOM will promote a common technical vocabulary conducive to developing national program policy. The editors have organized program

activities and performance measures into a framework of defined Activity Areas within Program Components. These categories were derived from previous Grant Guidance documents and Program Performance Guidelines, the recent Institute of Medicine report “Calling The Shots: Immunization Finance Policies and Practices,” input from the AIM working group and NIP’s in-house understanding of program structure and content. This framework encompasses the entire spectrum of activities with which immunization grantees are involved, including traditional program content and more recent program developments.

Although the IPOM is intended to be comprehensive, it is not an all-inclusive guide to immunization program content. We will depend on your feedback to improve and expand on the content and format in future editions.

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KEY to SYMBOLS

✓ Activities that CDC considers high priority

☞ Activities required by statute (i.e., Omnibus Budget Reconciliation Act of 1993 and Childhood Vaccine Injury Act of 1986) or necessitated by reports required by CDC

☆ Activities directly associated with raising immunization coverage

Division of Branch Roles and Responsibilities

related to the

Immunization Program Infrastructure

Program Components	Activity Areas	Branch Role
1. Program Management	Program Planning Vaccine Financing Staffing & Training Funding Allocation & Utilization Management Planning Partnerships & Collaborations	POB Lead, in collaboration with PSB on activities directly related to vaccine issues
2. Vaccine Management	Ordering, Distribution & Storage Vaccine Accountability (provider level)	PSB Lead
3. Registries	Provider Participation Registry Functions Registry Population	POB Lead, in collaboration with DMD
4. Provider Quality Assurance	Provider Education Provider Site Visits Perinatal Hepatitis B Prevention	POB Lead, in collaboration with PSB on activities related to the VFC-AFIX initiative
5. Service Delivery	Under-served Populations Medical Home Promotion	POB Lead
6. Consumer Information	Information Development & Dissemination Vaccine Benefit & Risk Communication	POB Lead
7. Surveillance	Disease Surveillance and Response VPD Reporting Perinatal Hepatitis B Screening Vaccine Safety	POB Lead
8. Population Assessment	General Population Assessments Special Population Assessments	POB Lead

ACRONYMS

Ab-negative	Antibody negative
ACP	American College of Physicians
AAP	American Academy of Pediatricians
AAFP	American Academy of Family Physicians
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
AKC	All Kids Count
AFIX	Assessment, Feedback, Incentive, and eXchange
AIM	Association of Immunization Managers
BRFSS	Behavioral Risk Factor Surveillance System
CASA	Clinical Assessment Software Application
CDC	Centers for Disease Control and Prevention
CNRA	Community Needs and Resource Assessment
CRS	Congenital Rubella Syndrome
CSF	Cerebrospinal Fluid
CSTE	Council of State and Territorial Epidemiologists
CY	Calendar year
DHHS	Department of Health and Human Services
FAX	Facsimile Transmission
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
FSR	Financial Status Reports
FY	Fiscal year
HAV	Hepatitis A virus
HEDIS	Health Plan Employers Data and Information Set
HBsAG	Hepatitis B Surface Antigen
HBIG	Hepatitis B Immune Globulin
Hib	*Haemophilus influenzae type B*
HIV	Human Immunodeficiency Virus
HL7	Health Level 7
HP 2010	Healthy People 2010
IAC	Immunization Action Coalition
IgM anti-HAV	IgM anti-hepatitis A virus
IgM anti-HBc	IgM anti-hepatitis B core antigen
IHS	Indian Health Service
IOM	Institute of Medicine
IPOM	Immunization Program Operations Manual
IPV	Inactivated poliovirus vaccine

ISD	Immunization Services Division
IV	Intravenous
LTC	Long Term Care
LQA	Lot Quality Assurance
M/CHCs	Migrant Community Health Centers
MCO	Managed Care Organization
MMR2	Measles, Mumps, Rubella second dose
MMWR	Morbidity and Mortality Weekly Report
MOU	Memoranda of Understanding
NCVIA	National Childhood Vaccine Injury Act
NEDSS	National Electronic Disease Surveillance System
NETSS	National Electronic Telecommunications System for Surveillance
NIC	National Immunization Conference
NIP	National Immunization Program
NIS	Nation Immunization Survey
NIIW	National Infant Immunization Week
NVAC	National Vaccine Advisory Committee
NVPO	Nation Vaccine Program Office
POB	Program Operations Branch
PON	Pockets of Need
SCHIP	State Children's Health Insurance Program
SOP	Standard Operating Procedure
STD	Sexually Transmitted Disease
TANF	Temporary Assistance for Needy Families
USDA	U. S. Department of Agriculture
VAERS	Vaccine Adverse Events Report System
VICP	National Vaccine Injury Compensation Program
VIS	Vaccine Information Statements
VPD	Vaccine Preventable Diseases
VFC	Vaccines For Children Program
VFC-AFIX	Vaccines For Children Program and Assessment, Feedback, Incentive and eXchange Collaborative Activity
WIC	Women, Infants and Children Nutrition Program

BUDGET CATEGORIES

Program Components	Cost Centers
1. Program Management	317 VFC Operations
2. Vaccine Management	317 VFC Ordering VFC Distribution
3. Registries	317 VFC
4. Provider Quality Assurance	317 VFC
5. Service Delivery	317
6. Consumer Information	317
7. Surveillance	317
8. Population Assessment	317

1 Program Management

Effective management of immunization programs (planning, organizing, budgeting, supervising, coordinating, directing, monitoring and evaluating) is necessary to expend federal, state, local and other funds as they were intended and to implement immunization-related activities appropriately. In most states the role of public health is changing (or has already changed) from *direct delivery* of immunization services to *assuring* appropriate delivery of those services by others. As a result, program managers may find it necessary to revise or expand their policies, procedures and staffing infrastructure to focus more attention on the assurance functions associated with vaccine financing, provider practices, consumer education and surveillance. This may require development of contracts, Memoranda of Understanding (MOUs) or less formal agreements and collaborations with other public and private entities.

Keywords:
Budgeting
Coalitions
Collaboration
Funding
Partnerships
Planning
Pandemic Influenza preparedness planning
Program evaluation
Resource allocation
Staffing
Vaccine needs estimates
Vaccine forecasting
Vaccine funding

In most areas, the financing of vaccines is a complex patchwork of funding mechanisms that include 317 and VFC funds, SCHIP, Medicare, state and local funding and variations of private health insurance. According to the IOM report on "Calling The Shots: Immunization Finance Policies and Practices," immunization programs have a responsibility to assure that these funding mechanisms provide adequate financing for vaccines recommended for all age groups so that vaccine cost is eliminated as a barrier to immunization.

The largest portion of any immunization program's budget is for the purchase of vaccines. Given the increasing cost of vaccines and the perishable nature of vaccine products, monitoring and accounting for vaccine products, especially those purchased with public funds is one of the most important management responsibilities of immunization programs.

An essential aspect of immunization program planning includes development of a pandemic influenza preparedness plan. Based on the morbidity and mortality resulting from the three major influenza pandemics which occurred earlier in the twentieth century, an influenza pandemic in the United States now could cause up to 207,000 deaths, 734,000 hospitalizations, 42 million outpatient visits, and 47 million additional illnesses in the United States alone. Grantees that do not have influenza pandemic plans should develop such plans. Grantees that do have plans will need to exercise such plans, evaluate the exercise, and revise their plans accordingly. (Ref to: **Attachment 1 – Pandemic Influenza Preparedness: Planning and Implementation.)**

References:

- 2002 VFC Program Operations Guide (CDC)
- Creating A Community Coalition – A Practical Guide (CDC)
- Calling The Shots: Immunization Finance Policies and Practices (IOM, 2000)
- VOFA (Vaccine Ordering and Forecasting Application) (CDC)
- Pandemic Influenza: A Planning Guide for State and Local Officials, version 2.1 (CDC NVPO) www.cdc,gov/od/nvpo/pandemicflu.htm
- Examples of state pandemic influenza preparedness plans (CSTE) www.cste.org
- FluAid software to project possible impact of a pandemic (CDC) www.cdc.gov/od/nvpo/pandemics
- Pandemic influenza scenario (CSTE). ASTHO's: *Preparedness Planning for State Health Officials –Nature's Terrorist Attack: Pandemic Influenza.* www.astho.org"
- CD-ROM of slides for presentations, (CDC) rstrikas@cdc.gov
- *Evaluating the Utilization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs* (available from DTQ1@CDC.GOV beginning August, 2001)

ACTIVITY AREAS

1. Program Planning
2. Vaccine Financing
3. Staffing and Training
4. Funding Allocation and Utilization
5. Management Planning
6. Partnerships and Collaborations

1.1 PROGRAM PLANNING

ACTIVITIES to plan an effective immunization program:

✓**1.1.1** Develop a comprehensive plan to assure full immunization of all citizens living in the program area. This plan should be the basis for the annual immunization grant application and in the program's internal strategic planning processes. *See 1.1.0 ELEMENTS of a Program Plan*.

1.1.0 ELEMENTS of a Program Plan

- Public clinic needs assessment strategies
- Documentation of program need and program capacity
- Long term objectives consistent with Healthy People 2010
- Strategies to assure immunizations for all age groups
- Prioritization of underserved and under immunized groups
- Measles elimination strategies
- A comprehensive pandemic influenza preparedness plan
- Vaccine financing plan, including strategies to maximize VFC
- New vaccine implementation plan (ad hoc)
- Vaccine accountability plan

1.1.2 Develop strategies to assess the need for public immunization services by determining why current clients are using existing public immunization clinics.
See: *Evaluating the Utilization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs* (available from DTQ1@CDC.GOV beginning August, 2001).

✓ ☞ **1.1.3** Identify and document program need (e.g., type and size of target populations, number to be served in the public sector, number of persons with health insurance covering vaccine, etc) and capacity of the program (number and location of clinic sites serving children under six years of age, adolescents and adults, number of immunization clinic sessions, etc.).

✓**1.1.4** Devise a strategy to ensure that all school-aged children receive two doses of measles-containing vaccine.

✓**1.1.5** Develop a pandemic influenza preparedness plan in collaboration with state and local emergency management agencies. States that already have plans in place should review them to assure that they are up to date, and conduct a test of the plan. One option to test plans is to do a tabletop exercise, using a pandemic scenario.
(refer to: **Attachment 1 – Pandemic Influenza Preparedness: Planning and Implementation.**)

✓ **1.1.6** Outline proposed adolescent and adult immunization activities to reach Healthy People 2010 objectives**.**

1.1.7 Conduct a comprehensive review of policies of health care institutions and insurance carriers that affect immunization of children, adolescents and adults.

✓ **1.1.8** Develop a strategy to assure that all private providers are educated about the *Standards for Pediatric and Adolescent Immunization Practices* (www.cdc.gov) and the *Standards for Adult Immunization Practices.*

✓ **1.1.9** Develop a strategy to assure that providers, including FQHCs, who serve Medicaid-eligible, uninsured and American Indian/Alaska Native patients are enrolled into the VFC program. In program areas with significant American Indian / Alaska Native populations, the plan should ensure access to immunization services for all age groups and immediate and consistent access to all VFC vaccines by American Indians and Alaska Natives.

1.2 VACCINE FINANCING

ACTIVITIES to estimate over-all public vaccine needs:

✓**1.2.1** Establish and/or maintain a program-wide vaccine supply policy based on eligibility criteria and/or target groups to be served and availability of public funds for vaccine purchase (VFC, 317, state/local, SCHIP, Medicare, etc.).

✓**1.2.2** At least semi-annually, project public vaccine needs for the upcoming 12 month ☞ period based on current and anticipated ACIP recommendations, population to be served, anticipated vaccine uptake, vaccine wastage rates, and state/local vaccine supply policy, and vaccine inventories.

1.2.3 Compare projected vaccine needs for the upcoming 12 month period based on previous history of vaccine usage with population-based vaccine need projections.

ACTIVITIES to ensure availability of adequate funding to meet vaccine needs:

✓**1.2.4** Seek funding for vaccine from state and local revenues, other federal grant funds, contributions from foundations, Medicaid and SCHIP to supplement 317 and VFC grants and ensure funding to cover the cost of all ACIP-recommended vaccines for underserved populations. *See 5.1.0 DEFINITION of Underserved Populations in Chapter 5. Service Delivery.*

✓**1.2.5** Support legislation or regulations that would require first dollar insurance coverage for immunization.

✓**1.2.6** Work with commercial MCOs and the State Medicaid agency to ensure that local health departments are appropriately reimbursed for vaccines and vaccine administration costs that are covered benefits. For commercial managed care organizations, this may require legislative or regulatory action. For Medicaid managed care organizations, cost reimbursement issues may be addressed contractually at the State Medicaid agency or Medicaid MCO level.

✓**1.2.7** Provide local health departments Information about Medicare coverage of influenza and Pneumococcal vaccines (and administration costs) and how to obtain reimbursement for these costs from Medicare**.**

✓**1.2.8** Support legislation, regulations or administrative/procedural changes that would enable or require local health departments to bill Medicare and commercial health insurance carriers for immunization services (including vaccine costs) delivered in local health department clinics.

✓**1.2.9** Submit a request for excise tax reimbursement of expired and wasted doses at least every 12 months.

✓**1.2.10** Monitor the amount of vaccine doses expired and wasted, maintain a secure quarantine area for wasted vaccines.

Performance Measure: *Amount and percent of vaccine doses expired/wasted*
Target: *Set by individual programs, but not more that 5%*

✓**1.2.11** Apportion vaccine purchases appropriately by funding source.
☞

Performance Measure: *Comparison of actual purchases by funding source with planned funding apportionments*
Target: *Concordance between the relative proportions of actual purchases using VFC, 317 and state/local by funds and planned funding apportionment as reflected in the current VFC Population Estimates Report*

✓**1.2.12** In conjunction with annual funding requests (grant application, state/local budget initiative, etc.) develop and update, as necessary, an annual vaccine spending plan which outlines population-based vaccine needs, funding sources and purchase schedules for each vaccine. Software for developing a vaccine spending plan is available from CDC in connection with submission of the annual immunization grant.

1.2.13 Work with federally qualified health centers to formally designate individual local health departments to provide VFC vaccine to under-insured children less than 18 years of age.

1.3 STAFFING AND TRAINING

ACTIVITIES to hire and train staff effectively:

✓**1.3.1** Establish position descriptions for each position and update them, as appropriate.

✓**1.3.2** Assign one or more staff the responsibility for each program component and reflect these responsibilities in the work plan for each staff member. Program staff should receive appropriate supervision through the organizational structure's chain of command. Supervisors should provide staff with regular, informal feedback about job performance and formally evaluate staff using the work plan as the basis.

1.3.3 Assign one or more staff the responsibility for coordinating perinatal hepatitis B prevention activities, including monitoring the reporting of HBsAg-positive women and ensuring case management of infants born to HBsAg-positive women.

1.3.4 Assign program staff to work with colleagues from other public and private organizations, as appropriate, to effectively coordinate program activities.

1.3.5 Arrange for key staff to attend CDC conferences and other training opportunities related to their specific duties.

1.4 FUNDING ALLOCATION AND UTILIZATION

ACTIVITIES to allocate and utilize program funds appropriately:

Refer to *Chapter 2.2 Vaccine Accountability* for additional details on activities related to maximizing vaccine resources.

✓**1.4.1** Establish a vaccine accountability plan which outlines policies, procedures and protocols directed at minimizing vaccine loss and wastage, prevents fraud and abuse of vaccines, ensures that VFC vaccines are administered only to VFC-eligible children, and apportions VFC, 317 and state vaccine purchases in accordance with the relative proportion of VFC, 317 and state children reported in the current VFC Population Estimates Report.

✓**1.4.2** Seek funding from all potential sources, including state and local revenues,
☞ federal grant funds (317, VFC and others), contributions from foundations, MCOs, Medicaid and SCHIP to ensure adequate support for operational costs to plan, develop and maintain a public health infrastructure which, over time, will assure high immunization coverage and low VPD morbidity among all age groups in the program area.

✓**1.4.3** Include in the annual immunization grant application an estimate of the
☞ amounts of 317 and VFC grant funds needed for each of the eight program components.

✓**1.4.4** Include in the annual grant application an estimate of the amounts of state, local
☞ and other funds budgeted for activities related to reducing VPDs and ensuring high immunization coverage for each of the eight program components.

1.4.5 Provide financial support for WIC screening and referral in areas where evidence suggests that WIC enrollees are significantly under immunized.

✓**1.4.6** Ensure that total grant expenditures and un-obligated balances are reported
☞ to CDC annually no later than 90 days after the end of each 12 month budget period. Separate financial accounting of 317 grant funds and VFC grant funds is required.

✓**1.4.7** Ensure that federal grant funds are used to supplement, not supplant state, or local resources.

✓**1.4.8** Develop and finalize the program's annual federal grant budget in
☞ consultation with the appropriate management staff and with designated NIP staff. The initial budget submission should represent a realistic estimate of the costs to fully implementing all the program components, activities and functions reflected in the current immunization Grant Guidance. The final grant budget, negotiated with designated NIP staff, should reflect financial realities and grantee priorities.

✓**1.4.9** Estimate the level of resources budgeted for each of the eight program ☞ components by allocating grant requests and other funding sources using the software application provided by CDC for this purpose.

✓**1.4.10** Monitor the approved grant budget to ensure funds are being expended as ☞ approved. Funds which are identified as potential carry-over should be redirected for other program activities immediately. Where required by CDC, redirection requests should be submitted before the deadline indicated by CDC and within a time frame that allows complete expenditure of the funds being redirected.

> ***Performance Measure:*** *Percentage of grant funds un-obligated at the end of the grant budget period*
> ***Target:*** *Set by individual grantee, but not more that 5%*

1.5 MANAGEMENT PLANNING

ACTIVITIES to develop and execute an effective management plan:

✓**1.5.1** Develop a management plan to clearly describe how the program objectives ☞ will be accomplished. The plan should include a description of the program's functional and organizational structure, and it should be reviewed and updated at least annually.

✓**1.5.2** Develop program objectives that are clear, realistic, specific, and time- ☞ phased, include quantitative, measurable targets, and are related to, or contribute directly to the achievement of national objectives.

✓**1.5.3** Establish procedures to regularly monitor and review progress to evaluate the impact of key interventions; and to adjust program activities and priorities based on the evaluation.

✓**1.5.4** Include in the management plan a description of methods that will be used to ensure that grant-funded staff is hired in accordance with the approved budget. The plan should include a description of how qualified staff will be recruited and hired in a timely fashion and what actions will be undertaken in the event of a hiring freeze to assure that critical program activities will be completed and grant funds expended appropriately.

1.6 PARTNERSHIPS and COLLABORATIONS

ACTIVITIES to assure program functions related to vaccine financing, service delivery, provider quality assurance, surveillance and consumer education:

For related activities, refer to *Chapter 4. Provider Quality Assurance* and *Chapter 6. Consumer Information*.

✓**1.6.1** Coordinate program planning and implementation of all program components between state and local health departments.

1.6.2 Develop a comprehensive partnering agenda that identifies and categorizes priority partners, and establishes and addresses mutually agreed upon specific, measurable objectives.

Performance Measure: *Number of priority partners with own or other than immunization program funding support and number with only immunization program funding support*
Target: *Set by individual program*

✓**1.6.3** Where appropriate, coordinate program planning and implementation with CDC's Indian Health Service (IHS) immunization coordinator and with IHS immunization coordinators at the regional and area office levels to assure full and consistent implementation of the VFC program among American Indian and Alaska Native populations.

✓**1.6.4** Provide administrative support to WIC to assist in operational screening, referral and other activities related to Immunization-WIC linkage. Support should include providing WIC directors with information about immunization coverage levels, both state-wide and within pockets of need, cooperative planning, budgeting, training of WIC staff, referral information, provider education materials, outreach, tracking and other services, as necessary to ensure that a comprehensive screening and referral system is in place that supplements WIC's limited role and responsibility. Immunization program support should be focused in areas where immunization coverage levels or coverage markers indicate the existence of significant under immunization.

1.6.5 Coordinate program planning and implementation with other public and private providers (including managed care organizations and community/migrant health centers) and other groups, organizations and agencies, especially those that represent or serve under-immunized populations.

✓**1.6.6** Build and participate in community-based and program-wide coalitions to ☞ promote specific activities or projects intended to assure immunization of all age groups. Coalition activity levels (frequency of meetings, number and type of

participants, etc) should be noted. *See 1.6.01 INGREDIENTS of a successful coalition.*

1.6.01 INGREDIENTS of a successful coalition:

- **Funding:** Seed money and/or in-kind contribution of time, physical space, phone, fax, etc. This gives a coalition identify.
- **Dedicated staff:** a person designated to keep things on track.
- **Broad-based membership:** A significant number of the coalition members are active on committee projects.
- **Completion of a Community Needs and Resource Assessment (CNRA).**
- **Strategic planning:** Basic information from the CNRA is assembled, analyzed and presented to the membership in facilitated strategic planning meetings.
- **Clear mission, goals, objectives and action plan:** Members are involved in creating, adopting and supporting a strategic plan which includes a time line, persons responsible, and budget.
- **Written guidelines, member roles and responsibilities:** This enables everyone to know what is expected of them.
- **Objectives** that are being met or not being met: Things are happening.
- **Meeting follow-up:** Staff person takes meeting notes, reminds members of action items, and provides encouragement, assistance and focus to members.
- **Fun:** Take time to have fun, get to know each other and network. Develop a team spirit and celebrate your efforts.

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- **Meeting follow-up:** Staff person takes meeting notes, reminds members of action items, provides encouragement, assistance and focus to members.
- **Fun:** Take time to have fun, get to know each other and network. Develop a team spirit and celebrate your efforts.

✓ **1.6.7** Establish and/or strengthen existing relationships/partnerships with state and local WIC and Temporary Assistance for Needy Families (TANF) programs.

See Chapter 5.1 Underserved populations.

1.6.8 Work with Medicaid, Medicare, SCHIP, MCOs, private insurance companies and private industries to improve coverage for vaccine, supplement vaccine administration costs by public and private health insurance plans, and contractually influence providers to give vaccines in accordance with ACIP recommendations.

1.6.9 Collaborate with the State Medicaid agency on the management and implementation of the VFC program and the recruitment of VFC providers.

1.6.10 Establish new and/or strengthen existing partnerships with private provider organizations, coalitions, community organizations, businesses, and other private groups to develop, implement and support intervention strategies aimed at raising immunization coverage levels among children, adolescents, and adults. *See 1.6.02 HOW TO create a successful community partnership*.

Performance Measure: *Number of new partnerships established with public and private organizations*
Target: *Set by individual program*

1.6.02 HOW TO create a successful community partnership:

- Involve the "community" from the start of the project. Being a partner means involvement in the conceptualization, planning, content, analysis, interpretation, writing and solution phases of a project.
- Understand the community's history, demographics and resources.
- Listen. Respect the different views and perspectives of the community.
- Solicit, acknowledge and address community concerns about the proposed research, prevention or intervention activity.
- The partners working with the local community must be active partners.
- Educate the community about *public health* and *prevention.*
- Build an infrastructure for partnerships such as community organizations, coalitions and working groups.
- Facilitate the community working together to define and solve its own problems.
- Identify community gatekeepers and leaders who should be part of the program.
- Realize that in collaborative work, personality, credibility, integrity and commitment matter.

1.6.11 Ensure that partnerships include all parties involved in child, adolescent and adult immunization issues: parents, providers, health departments, provider organizations, managed care organizations, health communicators, legal advisers, community leaders and agencies.

1.6.12 Provide leadership in the promotion of laws/rules/regulations for first dollar insurance coverage for immunizations and immunization requirements for schools, child care facilities, adult settings such as long term and acute care nursing homes, and reporting of VPD cases and positive laboratory tests (including HBsAg screening tests).

✓**1.6.13** Work with state and community partners to support new and enforce existing immunization requirements for schools, day care centers, and colleges/universities for all routinely recommended antigens, as appropriate.

✓**1.6.14** Collaborate with parent advocacy groups and other stakeholders to develop the registry and to assist with increasing child participation through registry promotion activities and other strategies designed to facilitate participation (e.g., "opt out" versus "opt in").

1.6.15 Work with primary care providers, their professional organizations, and MCOs to ensure appropriate and adequate immunization and provision of immunization information and counseling for their patients.

1.6.16 Work with hospitals, health maintenance organizations, laboratories and/or large group practices to establish and provide provider and patient education programs targeted to community or provider-specific immunization problems such as barriers to immunization, catch-up opportunities, and perinatal hepatitis B prevention screening and reporting activities.

> ***Performance Measure****: Percent of hospitals, health maintenance organizations and major group practices involved in partnerships to promote and provide patient immunization education programs on immunization*
> ***Target:*** *Set by individual program*

1.6.17 Include local television and radio network affiliates in community partnerships to facilitate delivery of immunization-related health messages to the community.

> ***Performance Measure:*** *Percent of local television and radio network affiliates and independent stations that have become partners with one or more community organizations around immunization issues*
> ***Target:*** *Set by individual program*

1.6.18 Develop and implement a recognition system to reward partners for their contributions in helping to achieve immunization goals and objectives.

> ***Performance Measure:*** *Number of partners and/or partnerships receiving recognition in media or at presentations for contribution*
> ***Target:*** *Set by individual program*

2 Vaccine Management

The high cost and perishable nature of vaccine products obligates state and local immunization programs to maintain efficient vaccine distribution systems and closely monitor vaccine handling and storage practices to minimize vaccine wastage and loss. Vaccine potency may be compromised through poor vaccine handling practices. As a result, immunization programs and their distribution contractors that order, store and distribute vaccines to providers have a critical responsibility to safeguard the products within their systems. They must have the proper equipment, materials, and expertise to correctly handle, store, package, and ship vaccines to providers. An efficient vaccine distribution system demands user-friendly ordering procedures, appropriate packing and shipping methods, a distribution arrangement that minimizes cost and vaccine handling, and documented accountability of every dose purchased.

Keywords:
Cold Chain
Vaccine Accounting
Vaccine Needs Projection
Vaccine Ordering
Vaccine Shipping
Vaccine Storage
VFC Program
VFC Physician Recruitment

Immunization programs also have a prime responsibility to assure appropriate use of public vaccine and to vigorously enforce measures to prevent fraud and abuse of public vaccine at the provider level. This is accomplished through provider education and quality assurance aspects of vaccine ordering, storage, handling, safe administration and wastage within the office or clinic.

For additional details on VFC program requirements, please refer to the current VFC Program Operations Guide published by CDC. Also see Chapter 4. Provider Quality Assurance.

ACTIVITY AREAS

2.1 Vaccine Ordering, Distribution and Storage Systems
2.2 Vaccine Accountability (Provider Level)

References:

- 2002 VFC Program Operations Guide (CDC)
- *Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals*, (CDC) (CD Rom 2003 Immunization Works)
- *Guidelines for Vaccine Packing and Shipping* (CDC)
- ACIP Recommendations: General Immunization, Adolescent Immunization, Adult Immunization and Vaccine-Specific Recommendations, (CDC) (CD Rom 2003 Immunization Works)
- Toolkit for Evaluating Immunization Clinic Attendance (available from Program Support Branch, NIP, (404) 639-8222. DTQ1@CDC.GOV

2.1 VACCINE ORDERING, DISTRIBUTION and STORAGE SYSTEMS

ACTIVITIES to maintain adequate inventories in the public vaccine distribution "pipeline."

✓ **2.1.1** Maintain an efficient system to distribute public vaccine. The system can be managed directly by the program or through contracts with specialized private pharmaceutical distributors or through a combination of both. *See 2.1.0 CHARACTERISTICS of an efficient vaccine distribution system.*

✓ **2.1.2** Order vaccine in accordance with an annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen. *See Chapter 1.2 Vaccine Financing*.

2.1.0 CHARACTERISTICS of an efficient vaccine distribution system

- Efficient (minimal distribution levels)
- Minimizes vaccine handling
- Low cost per dose shipped
- Secure (maintains cold chain)
- Reliable

ACTIVITIES to assure vaccines are delivered to providers in a timely manner:

✓ **2.1.3** Process provider vaccine orders in a timely, efficient and accurate manner.

> ***Performance Measure:*** *Number or percent [improvement] of providers responding positively to provider survey questions concerning timeliness, efficiency and accuracy of the processing of their vaccine orders*
> ***Target:*** *Set by individual program*

✓ **2.1.4** Supply all ACIP-recommended vaccines to VFC providers in accordance with current ☞ VFC-ACIP resolutions.

✓ **2.1.5** Supply all ACIP-recommended vaccines available to all public providers, including STD clinics, which serve under-insured children, adolescents, and/or high risk adults.

ACTIVITIES to assure that vaccines remain effective (potent):

✓ **2.1.6** Develop, regularly review, and, as necessary, update written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, shipping, tracking and disposal. SOPs should include contingencies for power outages, natural disasters and other emergencies that involve the physical relocation of vaccines.

✓ **2.1.7** Ensure that vaccines within the program's distribution system are handled, stored and shipped in accordance with CDC Guidelines. *See Vaccine Management*:

Recommendations for Handling and Storage of Selected Biologicals, (CDC) (CD Rom 2003 Immunization Works). Due to local temperature extremes, some states will find these recommendations to be inadequate. Packing and shipping procedures for these states should be documented and justified. Additional cost may also be justified.

✓ **2.1.8** Safeguard public vaccines by providing facility security such as refrigerator locks, temperature and burglar alarms, and restricted access to vaccine storage and handling areas. For large vaccine depots, back-up generators should be installed and regularly tested.

✓ **2.1.9** Rotate vaccine inventories to ensure that vaccine received first is shipped out first.

2.1.10 Maintain a secure quarantine area for wasted vaccines.

✓ **2.1.11** Provide training on appropriate vaccine ordering, handling, storage, shipping and accounting to all staff and their back-ups, for both program and/or contractor employees involved in the public vaccine distribution system. Training should be prioritized based on findings of quality assurance reviews of vaccine ordering, storage, handling and accounting practices within the state/local public vaccine distribution system.

Performance Measure*: Number of vaccine management trainings conducted*
Target: *Set by individual program*

2.1.12 Request VFC providers to notify the program of any vaccine doses which will expire before they will be able to administer it. Whenever the cold chain can be assured, redistribute short-dated vaccines to high volume providers who are able to administer it before it expires.

2.2 VACCINE ACCOUNTABILITY (Provider Level)

ACTIVITIES to ensure the appropriate use of vaccine purchased with VFC and other public funds at the provider level and to prevent fraudulent use of vaccines purchased with public funds:

For more activities related to vaccine accountability, refer to Chapter 4. Provider Quality Assurance.

✓ **2.2.1** Use VACMAN software application for processing vaccine orders, distributing vaccines and other vaccine management activities.

✓ **2.2.2** Immediately report to CDC instances of possible fraudulent use of vaccine purchased with federal funds. Work closely with Medicaid and other appropriate state legal authorities in VFC fraud investigations and complete and submit to your NIP, VFC Consultant a preliminary investigation within five working days of the initial report.

✓ **2.2.3** Require providers to update and submit updated Provider Profiles at least ☞ annually. The name, medical license number and Medicaid provider number (if applicable) of each provider practicing at each enrolled site should be documented. VFC site documentation and VFC Provider Profiles should be maintained for at least three years.

> ***Performance Measure:*** *Percent of provider sites enrolled in the VFC Program that have completed a Provider Profile in the last year*
> ***TARGET:*** *100%*

✓ **2.2.4** Ensure that VFC providers accurately identify the number of VFC-eligible and ☞ non-VFC-eligible children served by comparing Provider Profiles with information obtained during on-site visits. *See Chapter 4.2 Provider Site Visits for additional details.*

✓ **2.2.5** Review and approve provider vaccine orders, ensuring that the orders reflect each provider's vaccine needs and are consistent with the number of VFC-eligible children reported in the most recent Provider Profile.

> ***Performance Measure:*** *Number of doses of VFC and non-VFC vaccine shipped to each provider annually*
> ***Target:*** *Concordance between the amount of vaccine shipped to each provider and the amounts reflected in the Provider's Profile*

✓ **2.2.6** Monitor providers' use of public vaccine through bench marking, doses administered reports and/or other techniques; evaluate individual provider usage by comparing with prior usage.

2.2.7 Survey providers enrolled in the VFC program at least biennially to determine their satisfaction with the program.

ACTIVITIES to minimize and document vaccine loss and wastage at the provider level:

✓ **2.2.8** Document expired and wasted doses of public vaccine by developing and implementing written procedures for providers to report and responds to all losses resulting from vaccine expiration, wastage, and compromised cold chain.

> ***Performance Measure:*** *Number of doses [and dollar value] of vaccine lost (expired and wasted)*
> ***Target:*** *Concordance between doses reported lost with an independent calculation of doses lost using inventory and doses administered reports.* Total doses lost, wasted, or unaccounted for should not exceed 5%.

3 Immunization Registries

Healthy People 2010 have established the goal of increasing to 95% the proportion of children from birth through age 5 enrolled in a fully operational immunization registry. In 1993, NIP began awarding planning grants to develop immunization registries in every state. Since then, federal funds have been awarded to promote and support the development of registries throughout the U.S. as a key data resource to provide the information needed to improve and sustain high levels of coverage.

Registries are population-based computerized information systems that may be implemented at the community, state, or multi-state levels and represent an important tool for tracking immunization records of an ever-increasing mobile population. Immunization registries consolidate vaccination records for children from multiple providers, provide vaccination needs assessments for each child, generate reminder/recall notices, produce official vaccination records, and provide practice-and community-based vaccination coverage assessments.

Keywords:
Computerized Information System
Data Exchange
Functional Standards
Health Level 7 (HL7)
Immunization Records
Registry
Reminder/Recall
Vaccine Coverage Assessment

References: Each document listed below is available on the CDC/NIP Immunization Registry Clearinghouse website at: www.cdc.gov/nip/registry

- Development of Community- and State-Based Immunization Registries (NVAC)
- Community Immunization Registries Manual, Chapter II: Confidentiality (CDC/AKC)
- Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard protocol (CDC) (Implementation Guide Version 2.1, September 2002)
- Recommended Core Data Set for State Immunization Information Systems (CDC)
- Technical Development Guidance (revised Programmers Evaluation Guide) (CDC)
- Progress in Development of Immunization Registries - United States 2000 (MMWR January 12, 2001).
- Registry Standards of Excellence in Support of an Immunization Program (American Immunization Registry Association's Programmatic Registry Operations Workgroup, October 15, 2002)

ACTIVITY AREAS

3.1 Registry Functions
3.2 Provider Participation
3.3 Registry Population

3.1 REGISTRY FUNCTIONS

ACTIVITIES to plan, develop, and implement appropriate functioning of immunization registries:

✓ **3.1.1** Develop a three-year implementation plan to ensure reaching the *Healthy* ☞ *People 2010* registry goal. The plan should include a vision, interim goals, objectives, time lines, and assigned responsibilities associated with attaining and sustaining each of the 12 functional standards. It should also address all activities associated with registry planning, development, implementation, maintenance, and evaluation; and it should include a description of activities related to quality assurance, written privacy and confidentiality policy/protocols, and performance monitoring. The plan should be updated at least annually.

✓ **3.1.2** As funding permits, design and construct (an) immunization registry or ☞ registries in accordance with the12 functional standards of operation. *See 3.1.0 FUNCTIONAL STANDARDS for immunization registries.*

Performance measure: *Percentage of functional standards attained*

 Target: *Annual progress toward meeting all 12 functional standards*

3.1.0 FUNCTIONAL STANDARDS for immunization registries:

- Electronically stores data on all NVAC-approved core data elements
- Establishes a registry record within six weeks of birth for each newborn child born in the catchments area
- Enables access to and retrieval of immunization information in the registry at the time of the encounter
- Receives and processes immunization information within one month of vaccine administration
- Protects the confidentiality of medical information
- Ensures the security of medical information
- Exchanges immunization records using Health Level Seven (HL7) standards
- Automatically determines the routine childhood immunization(s) needed, in compliance with current recommendations of the ACIP, when an individual presents for a scheduled immunization
- Automatically identifies individuals due/late for immunization(s) to enable the production of reminder/recall notifications
- Automatically produces immunization coverage reports by providers, age groups, and geographic areas
- Produces official immunization records
- Promotes accuracy and completeness of registry data

3.2 PROVIDER PARTICIPATION

ACTIVITIES to ensure that all immunization provider sites routinely submit immunization records on children < 6 years of age to the registry (in program areas where a registry is operational):

✓ **3.2.1** Increase the percentage of public and private provider sites participating in the registry. Collaborate with provider organizations and other stakeholders in the registry's catchments area to assist with provider recruitment, planning and implementation.

> ***Performance Measure:*** *Percentage of public provider sites that routinely submit immunization events to the registry on children < 6 years of age*
> ***Target:*** *Progress toward 100% set by individual programs*
>
> ***Performance Measure:*** *Number and percentage of private provider sites submitting immunization events to the registry on children < 6 years of age*
> ***Target:*** *Progress toward 95% set by individual programs*

✓ **3.2.2** Establish a plan for recruiting, supporting, and retaining providers in the registry.

✓ **3.2.3** Use registry data to demonstrate registry usefulness such as monitoring the implementation of changes in the vaccine schedule, assessing vaccine coverage, and driving public health decision-making.

✓ **3.2.4** Establish sufficient training, a help desk, and other resources necessary to ensure timely, on-going support to participating providers.

✓ **3.2.5** Implement strategies to ensure the registry enables data exchange with providers in a timely, efficient, and cost-effective manner (e.g., avoid duplicate data entry).

✓ **3.2.6** Implement data quality measures to ensure the completeness, accuracy, and timeliness of registry data (e.g., lot quality assurance sampling).

3.2.7 Collaborate with providers, provider organizations and other stakeholders to develop the registry - or if already developed - to assist with implementation.

3.3 REGISTRY POPULATION

ACTIVITIES to ensure that immunization records on children <6 years of age are recorded in the registry:

✓ **3.3.1** In program areas where an immunization registry is operational, increase the ☞ percentage of children participating in the registry.

> ***Performance Measure:*** *Percentage [increase] of children <6 years of age in the registry's catchments area who are participating in the registry. Progress made will be evaluated in the Immunization Registry Annual Report and NIP annual grantee site visits*
> ***TARGET:*** *Progress toward 95%* set by individual programs

3.3.2 Promote activities and other strategies designed to facilitate participation (e.g., "opt out" versus "opt in").

✓ **3.3.3** Develop a plan for increasing child participation in registries using strategies such as linking with WIC and VFC programs.

4 Provider Quality Assurance

Improving immunization practices in providers' offices is one of the most effective methods to increase immunization coverage. The role of the Immunization Program is to oversee quality assurance of all immunization practices in the providers' offices.

Examples of quality assurance activities includes: 1) evaluating a providers' vaccine handling procedures, 2) assessing a provider's immunization practices, 3) providing specialized training for provider's staff and 4) promoting accepted standards for immunization practices. Continuous quality improvement in these areas ensures that viable vaccines are administered in accordance with the recommended schedule, opportunities to vaccinate are not missed, and barriers to vaccinate are minimized.

Keywords:
ACIP recommendations
AFIX
Barriers to immunization
In-service training
Missed opportunities to vaccinate
Peer Training
Perinatal Hepatitis B Prevention
Provider assessment
Provider compliance
Provider education & training
Satellite training course
Standards for Adult Immunization Practices
Standards for Pediatric Immunization Practices
Vaccine handling
VFC requirements
VFC fraud

Monitoring quality assurance entails conducting site visits to providers' offices to: 1) review VFC eligibility,, vaccine ordering, storage and handling procedures and 2) to provide training when providers' practices in these areas are not adequate. On the rare occasions when fraud and abuse of public vaccine is identified, immunization programs are responsible for conducting an investigation and reporting these instances to the proper authorities. Program managers should refer to the current VFC Program Operations Guide for additional information about vaccine accountability and quality assurance.

Assessing a provider's level of immunization coverage is another role of the Immunization Program. One of the most effective strategies to improve immunization coverage called *AFIX* involves **A**ssessing immunization records, **F**eedback of results to the provider, offering **I**ncentives such as rewards or praise to the provider, and e**X**change of results to stimulate them to identify and implement effective strategies to increase immunization coverage Beginning in 2000, CDC made additional VFC funding available to increase the number of site visits to private VFC providers and to incorporate AFIX activities into traditional VFC site visits.

Other evidence-based strategies that reduce barriers to immunizations and improve immunization coverage include 1) provider and patient reminder/recall systems, 2)

reducing out-of-pocket vaccine and vaccine administration expenses, and 3) incorporating standing orders for immunizations into the medical setting.

ACTIVITY AREAS

4.1 Provider Education
4.2 Provider Site Visits
4.3 Perinatal Hepatitis B Prevention

References:

- 2002 VFC Program Operations Guide (CDC)
- *Standards for Pediatric and Adolescent Immunization Practices* (CDC) www.cdc.gov/mmwr/PDF/rr/rr4205.pdf
- *Standards for Adult Immunization Practices - Draft,* (CDC)
- Recommendations of the Advisory Committee on Immunization Practices: Programmatic Strategies to Increase Vaccination Rates -- Assessment and Feedback of Provider-Based Vaccination Coverage Information *www.cdc.gov/mmwr/preview/mmwrhtml/00040662.htm*
- *Managing a Hepatitis B Prevention Program: A Guide to Life as a Program Coordinator,* (CDC)
- American College of Obstetricians and Gynecologists (ACOG) Guidelines for Rubella (prenatal testing/postpartum vaccination) www.acog.org
- Vaccine-Preventable Disease: Improving Vaccination Coverage in Children, Adolescents and Adults. *Guide to Community Preventive Services*, *Task Force for Community Preventive Service* (CDC) (MMWR 1999, 48 RR:8:1-15)
- *Vaccine Information Statements: What you need to know,* (CDC) (CD Rom 2001 Immunization Works)
- VAERS web site www.VAERS.org
- ACIP Statement on Routinely Recommended Childhood Adolescent, Adult and General Immunization, (CDC) (CD Rom 2001 Immunization Works)
- Epidemiology and Prevention of Vaccine Preventable Diseases (The Pink Book), (CDC, 7th Edition, April 10, 2002) (CD Rom 2001 Immunization Works)
- VFC-AFIX (CDC) (CD Rom 2001 Immunization Works)
- *Evaluating the Utililization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs*, available from the Program Support Branch at 404-639-8222, beginning August, 2001)
- *AFIX website: www.cdc.gov\nip\AFIX*

4.1 PROVIDER EDUCATION

ACTIVITIES to educate providers about strategies that optimize immunization practices and improve immunization coverage.

☞ **For more information on how provider education activities are impacted by HIPAA, please refer to the MMWR Supplement dated May 2, 2003, "HIPAA Privacy Rule and Public Health – Guidance from CDC and the U.S. Department of Health and Human Services" in Appendix XX**

4.1.1 Develop and implement a communication plan to disseminate immunization messages and information to providers. The plan should clearly identify the state's communication objectives and the strategies designed to achieve these objectives.

✓ **4.1.2** Distribute immunization information to immunization providers and to provider organizations (e.g., ACIP, AAP, AAFP, ACP) through special mailings, newsletters, communicable disease bulletins, websites, and email listserves.

See *4.1.01 INFORMATION PROVIDERS NEED to Optimize Immunization Practices*.

4.1.01 INFORMATION PROVIDERS NEED to know to optimize immunization practices:
General Programmatic Topics

- ACIP recommendations for infants, children, adolescents and adults
- Information about the VFC program, its benefits to their eligible populations, and how to enroll
- Use of Vaccine Information Statements
- State laws, rules and regulations regarding immunization requirements for school entry, day care, nursing homes, colleges and universities, and employment
- Medicare, Medicaid, SCHIP and other public and private health insurance plans enrollment and claims procedures
- VFC vaccine ordering procedures and appropriate vaccine handling and storage requirement
- Evidence-based vaccine strategies to improve immunization coverage
- Provider assessment methods and standards such as CASA, LQA, HEDIS, etc.
- Immunization registries -- availability, benefits, enrollment procedures and submitting immunization records
- Training and educational opportunities, such as CDC-sponsored VPD courses, distance-learning methods such as satellite broadcasts and web-based training, VFC Workshops, State/local immunization-related in-service seminars and the annual National Immunization Conference
- Systems to remind patients of immunizations needed and to recall patients who are late for receiving needed immunizations

✓ **4.1.3** Distribute and promote *Standards of Pediatric and Adolescent Immunization Practices* and *Standards for Adult Immunization Practices* to all public and private immunization providers directly or in collaboration with public and private provider organizations using mailings, newsletters, and other publications. *See 4.1.02 INFORMATION PROVIDERS NEED to Optimize Immunization Practices: Summary of Standards for Pediatric, Adolescent and Adult Immunization Practices.*

4.1.02 INFORMATION PROVIDERS NEED to Optimize Immunization Practices: Summary of Standards for Pediatric, Adolescent and Adult Immunization Practices

- Immunization services are readily available to parents, guardians, and adult patients
- Vaccinations are coordinated with other health services when possible
- Barriers to receiving vaccines (e.g., requiring a physical exam before administering vaccines) are eliminated
- Patient's out-of-pocket expenses are eliminated or minimized
- Immunization status of each patient is routinely reviewed
- Patients are evaluated for contraindications for vaccination and only valid contraindications are followed
- Patients are informed about risks and benefits of immunization in a culturally-appropriate manner and in easy-to-understand language - "Vaccination Information Statements" are provided before immunizations are given
- Written protocols concerning all aspects of immunization such as vaccine storage and handling, vaccination schedules, vaccine administration, record maintenance, etc., are available at all locations where vaccines are administered
- Provider staff are adequately trained in properly administering vaccines
- All recommended vaccine doses are administered at the same visit
- Patient immunization office records are accurate, complete and easily accessible, and patients are provided with an updated 'shot card' at each visit
- All office/clinic personnel having contact with parents, guardians, and patients are appropriately immunized
- Adverse events following vaccination are reported promptly to VAERS
- Reminder/recall systems are instituted and used
- Standing orders for vaccinations are employed
- Provider coverage and immunization practices are assessed regularly

4.1.4 Utilize all communication tools with a provider to promote provider-based strategies to improve immunization practices and coverage.

Performance Measure*: Increase in the number of individual and group trainings, including state and regional conferences, site visits, newsletters, and websites that focus on strategies to increase immunization coverage in both private and public immunization clinics.*
Targets: *Set by individual program*

4.1.5 Communicate with immunization providers to ensure that they access CDC, state and local agency web sites on immunizations.

Performance Measure*: Periodically, conduct a survey to determine whether immunization providers are accessing various websites and usefulness of websites.*
Targets: *Set by individual program*

ACTIVITIES to train providers on immunization practices and requirements:

✓ **4.1.6** Conduct presentations, seminars, workshops and in-service training on ☆ immunization related topics for public and private health care professionals in collaboration with physician, nurse, hospital and public health professional organizations. See: *4.1.0 INFORMATION Providers Need to Know to Optimize Immunization Practices.*

Performance Measure: *Number of presentations, workshops, etc., delivered*
Performance Measure: *Number of participants for each presentation, workshop, etc., by discipline and institution (physician, nurse, public, private, etc.)*
Performance Measure: *Number of training sessions concerning VFC-AFIX or other evidenced-based interventions to improve coverage*
Targets: *Set by individual program*

✓ **4.1.7** In collaboration with provider organizations such as AAP and AAFP, use trained ☆ peer physicians to conduct a practice-based seminars on immunization basics for private providers. See *4.1.02 INFORMATION Providers Need to Know to Optimize Immunization Practices*.

Performance Measure: *Number of seminars conducted using trained physician peers.*
Target: *Set by individual program*

✓ **4.1.8** Sponsor CDC distance-learning opportunities such as the CDC satellite broadcasts and web-based training on vaccine preventable diseases and immunization issues.

Performance Measure: *Number of participants for each satellite course by attendee category (physician, nurse, public, private, etc.)*
Target: *Set by individual program*

✓ **4.1.9** Conduct workshops for public and private VFC providers to provide instruction on vaccine handling and management techniques, VFC program eligibility and screening for children and adolescents, and required VFC reports.

Performance Measure: *Number and percent of public and private providers attending the workshops, by provider type*

Target: *Set by individual program*

4.1.10 During workshops, courses and in-service training sessions, measure providers' level of knowledge and compliance with pediatric, adolescent and adult practice standards.

Performance Measure: Number of pre and post tests administered at courses and in-service training sessions.
Performance Measure: % improvement in providers' knowledge of and compliance with pediatric, adolescent and adult immunization practice standards.
Target: To be set by individual program.

ACTIVITIES to ensure that providers are informed about vaccine safety issues and requirements:

See: *Chapter 6 Consumer Information* and *Chapter 7.4 Vaccine Safety* for additional activities related to vaccine safety and the Vaccine Injury Compensation Program.

✓ **4.1.11** Maintain a communication system (newsletter, list serve, etc.) to address vaccine safety issues and controversies, including media and CDC or FDA statements. Use the communication system to disseminate vaccine safety information.

✓ **4.1.12** Remind all providers of their responsibility to inform their patients of the Vaccine Injury Compensation Program (VICP) and to discuss and answer client questions concerning vaccine benefits and risks, contraindications, adverse events and the steps to follow if an adverse event occurs. See: *4.1.03 PROVIDER RESPONSIBILITIES under the VICP.*

4.1.03 PROVIDER RESPONSIBILITIES under the National Vaccine Injury Compensation Program
✓ Provide their clients (or their parents/legal representative) prior to immunization the most current Vaccine Information Statement (VIS) for each vaccine
✓ Ensure that clients read or have read to them the VIS

✓ **4.1.13** Disseminate detailed information to providers and to provider organizations regarding the appropriate use of VIS (CDC pamphlet: *Vaccine Information Statements: what you need to know)*

Performance Measure: *Number of direct or collaborative efforts to promote VIS awareness and use among providers.*
Performance Measure: *As assessed through VFC site visits, the number and percent of providers using VIS correctly.*
Target: *100% of VFC enrolled providers.*

✓ **4.1.14** Disseminate information about the Vaccine Adverse Events Reporting Systems (VAERS), which adverse events must or may be reported and the reporting process, to all concerned. Reach all providers directly and/or collaboratively with provider organizations through mailings, meetings, and educational materials.

Performance Measure: *Number of direct or collaborative efforts to promote awareness, importance and appropriate use of VAERS and VAERS forms among providers*
Target: *Set by individual program*

✓ **4.1.15** Assure that providers are informed, either directly or collaboratively with provider organizations, of current and new vaccines covered by the National Childhood Vaccine Injury Act and of the federal requirement for record keeping content.

Performance Measure: *Number of direct or collaborative efforts to educate and promote the National Childhood Vaccine Injury Act and its content among providers*
Target: *Set by individual program*

ACTIVITIES to ensure providers are informed about VPD reporting and related requirements:

✓ **4.1.16** Disseminate information on legal requirements and procedures for reporting of vaccine preventable diseases to state/local health departments (directly and/or through provider organization mailings, publications, trainings and education materials).

Performance Measure: *Number of direct or collaborative efforts to educate and promote VPD reporting.*
Performance Measure: *Percent increase in providers reporting vaccine preventable diseases to state/local health departments.*
Target: *Set by individual program*

4.2 PROVIDER SITE VISITS

ACTIVITIES to assure appropriate vaccine handling procedures and compliance with VFC accounting requirements:

☞ **For more information on how provider site visit activities are impacted by HIPAA, please refer to the MMWR Supplement dated May 2, 2003, "HIPAA Privacy Rule and Public Health – Guidance from CDC and the U.S. Department of Health and Human Services" in Appendix XX**

✓ **4.2.1** Conduct annual site visits to providers receiving publicly funded vaccine ☞ (preferably in combination with a provider AFIX visit) to observe and evaluate critical vaccine management procedures and compliance with VFC program requirements. *See 4.2.01 WHAT TO OBSERVE AND EVALUATE during provider site visits. Refer to the current VFC Program Operations Guide for detailed information on conducting provider site visits.*

Performance Measure: *Number and percent of public and private VFC provider site visits completed annually*
Target: *Not less than 25% of the total number of enrolled VFC providers.*

Performance Measure: *Daily temperature log entries for all vaccine storage units under the control of state/local immunization programs or their contractors*
Performance Measure: *100% of all children are screened to determine VFC eligibility in each VFC provider site.*
Performance Measure: *100% of all VFC providers are reporting all wasted and expired vaccines.*
Performance Measure: *100% of all VFC providers can demonstrate the physical security of publicly funded vaccine.*
Performance Measure: *100% of all VFC providers are familiar with and utilize the vaccine ordering procedures.*
Performance Measure: *100% of all VFC providers will be trained on procedures for routine and emergency vaccine storage and handling.*

4.2.01 WHAT TO OBSERVE AND EVALUATE during provider site visits:

- Quality and appropriate use of vaccine storage facilities
- Use and review of temperature logs
- Reporting and disposal of wasted and expired antigens
- Physical security of vaccine (restriction of access, refrigerator locks, and burglar alarms)
- Vaccine ordering procedures
- Accuracy of information on the VFC Provider Profile
- Quality, consistency and documentation of eligibility screening
- Staff training on procedures for routine and emergency vaccine storage and handling.

✓ **4.2.2** Provide immediate training on appropriate vaccine ordering, handling, storage and accounting, as needed, to the relevant provider office staff. Document all training provided and follow-up with providers on each recommendation.

✓ **4.2.3** Identify, investigate and prevent fraud and abuse of 317 vaccines and VFC vaccines. If VFC vaccine is involved, collaborate with the State Medicaid Program.

✓**4.2.4** Complete a written report of all VFC site visits and enter results into an electronic database within an established time frame. Identify and monitor providers who are deficient in implementing any of the VFC requirements.

4.2.5 Prioritize VFC provider site visits with emphasis on large volume practices and high-risk or underserved populations.

4.2.6 Document the name, medical license number and Medicaid provider number (if applicable) of each provider practicing at an enrolled site.

4.2.7 Conduct a survey to determine VFC-enrolled provider satisfaction with VFC program at least biennially.

✓ **4.2.8** Validate public clinic VFC profiles by analyzing the demographic information of current clients using public immunization clinics. See: *Evaluating the Utilization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs*, available from the Program Support Branch at (404) 639-8222 beginning August, 2001.

ACTIVITIES to assure that providers identify and appropriately immunize specific high-risk patients**:**

✓ **4.2.9** During site visits, evaluate providers' knowledge and practices
☆ concerning the recommended immunization schedule and their procedures to identify and immunize patients at high-risk of under-immunization or infection with VPDs.

Performance Measure: *Number of public and private providers with established procedures to identify and appropriately immunize high risk patients*
Target: *Set by individual program*

✓ **4.2.10** Work with the peer review organizations to promote written policies and standing orders for immunization in long-term care (LTC) facilities, such as nursing home and assisted-living facilities.

Performance Measure: *Number and percentage point increase of LTC facilities routinely following standing orders for immunizations*
Target: *Set by individual program*

✓ **4.2.11** Inform providers of prenatal care, obstetric services and post delivery follow-up of newborns about the need for post-partum rubella vaccination of rubella Ab-negative women before departure from the hospital.

Performance Measurement: *% of rubella Ab-negative women who receive rubella vaccination before discharge from the hospital.*
Target: *Conduct one state or project wide hospital record review at least every 3 years.*

ACTIVITIES to improve immunization coverage by improving provider immunization practices through AFIX, reminder/recall, standing orders and other evidence-based provider interventions:

Healthy People 2010 Objective on Provider Assessments of Immunization Levels:

14-25: Increase the proportion of providers who have measured the vaccination coverage levels among children in their practice population within the past 2 years.

Target and Baseline:

Objective	Increase in Providers Measuring Vaccination Levels	1997	2010
14-25a.	Public health providers	66%	90%
14-25b.	Private providers	6%	90%

Target setting method: 36% improvement for public health providers; 1400% improvement for private providers.

✓ **4.2.12** Conduct AFIX provider visits to public and private VFC provider sites ☞ (preferably in combination with a provider site visit) to assess immunization practices and make recommendations for improvement.

Performance Measure: *Percent of public and private VFC providers assessed annually using the AFIX methodology*
Target*: At least 25% of all enrolled VFC providers.*

Performance Measure: *Percent of public and private VFC providers assessed who receive face to face feedback within two weeks of assessment.*
Target: *100% of all public and private providers who receive an AFIX visit should receive face to face feedback, in a timely manner, preferably within two weeks.*

✓ **4.2.13** Prioritize assessments with emphasis on relatively large volume practices ☞ and high-risk or underserved populations.

Performance Measure: *Percent of assessments conducted in large volume/high risk/underserved populations*
Target: *At least 50% of all high volume practices and those practices that provide immunizations to high-risk and underserved populations.*

✓ **4.2.14** Use CASA, mini-CASA, and/or a hybrid of these methodologies that
☞ incorporates Lot Quality Assurance Sampling as an assessment standard. For face to face feedback to the physician and office staff, use specific cases of missed opportunities to vaccinate as case-based diagnostic examples.

- **4.2.15** Within 12 months, repeat assessments of the largest public and private providers with the lowest coverage levels should be conducted and included as part of the total number of AFIX visits conducted for the calendar year.

Performance Measure: *Percent of assessments each year that are repeats.*
Target*: Set by individual programs based on the number of poor performing providers.*

✓ **4.2.16** Collaborate with public and private provider organizations, migrant/community health centers and MCOs to promote provider assessments and other evidence-based strategies to improve immunization coverage levels.

✓ **4.2.17** Collaborate with organizations that routinely serve adolescents and adults such as: 1) colleges and universities, and 2) those serving high risk adolescents and adult clients providers, such as nursing homes, STD clinics, and correctional facilities, to adapt assessment tools and assessment methods to meet the needs of their specific provider settings.

Performance Measure: *The number and percent of organizations that are assessing immunization coverage of their clients/enrollees, by type of organization, age group and vaccine.*
Target: *Set by individual program*

✓ **4.2.18** Complete the Incentive and eXchange part of the AFIX process by presenting
☞ provider assessment outcomes at state/local immunization meetings and
☆ professional meetings (MCO, AAP, AAFP); compare results among provider peer-groups, exchange ideas for improving provider practices, and award high-performers.

✓ **4.2.19** Promote the use of reminder/recall systems during AFIX visits
☆ See: *4.2.02 DEFINITIONS of Reminder / Recall*.

Performance Measure: *Percent [point increase] of providers who routinely use functional reminder/recall systems.*
Target: *Set by individual programs*

4.2.02 DEFINITIONS of Reminder / Recall:

- A reminder system provides a routine reminder of an upcoming immunization appointment
- A recall system provides routine notification of a missed appointment or overdue immunization and reschedules it
- Centralized systems that notify providers of their client's upcoming or missed appointments are called provider reminder/recall systems

✓ **4.2.20** Incorporate the pediatric, adolescent and adult immunization practice standards into protocols for conducting quality assurance reviews of public clinics and VFC provider sites. *See 4.1.02 Summary of Standards for Pediatric, Adolescent and Adult Immunization Practices*.

Performance Measure: *Number and percent [increase] of public and private providers who have implemented 75% or more of the Standards, by type of provider (e.g., pediatrician, family practice, and internist) and type of standard (pediatric, adolescent or adult) (Do health departments really ensure that each provider is complying with the standards?)*
Target*: Set by individual program*

Performance Measure: *Number and percent [increase] of VFC private and public providers who state that they routinely provide or update 'shot cards' at each visit.*

Performance Measure: *Decrease in the percentage of providers charging out-of-pocket vaccine or vaccine administration costs to client*
Targets: *Set by individual program*

✓ **4.2.21** During quality assurance reviews of public clinics, review and emphasize elements of the ☆ *Standards* that focus on removing barriers to immunization such as vaccine administration fees, physical exam requirements, lengthy waits, and prerequisite enrollment in other clinics. Promote the use of standing orders for immunizations, policies to give all recommended immunizations simultaneously, and procedures for providing and updating client-held immunization records.

Performance Measure: *Percent of public immunization clinics that are implementing the key Standards*
Target: *100% of all public immunization clinics.*

4.2.22 Encourage all public and private VFC providers to develop or improve patient-oriented and community-based approaches by seeking the input (who is to seek input? State immunization program or providers? And if its providers, are they really going to conduct focus groups, which is what this is talking about, of their clinic patients?) of underserved clinic patients on how to better serve their immunization needs and provide more user-friendly services.

4.3 PERINATAL HEPATITIS B PREVENTION

For additional guidelines on perinatal hepatitis B prevention, refer to *Managing a Hepatitis B Prevention Program - A Guide to Life as a Program Coordinator.*

For additional activities related to perinatal hepatitis B prevention, please refer to Chapter 5: Service Delivery, Activity 5.1.10 and Chapter 7: Surveillance, Activities 7.1.19-20, and section 7.3 – Perinatal Hepatitis B Screening

ACTIVITIES to ensure provider access to information on perinatal hepatitis B prevention:

☞ **For more information on how perinatal hepatitis B prevention activities are impacted by HIPAA, please refer to the MMWR Supplement dated May 2, 2003, "HIPAA Privacy Rule and Public Health – Guidance from CDC and the U.S. Department of Health and Human Services" in Appendix XX**

4.3.1 Write a protocol for perinatal hepatitis B prevention that includes information about the program and the procedures for reporting HBsAg-positive women and their infants to the health department. Distribute the protocol to local health departments, prenatal care providers, delivery hospitals and laboratories. *See 4.3.01 INFORMATION PROVIDERS NEED to prevent perinatal transmission of hepatitis B.*

4.3.01 INFORMATION PROVIDERS NEED to prevent perinatal hepatitis B transmission:

- Recommendations/Requirements for HBsAg screening of all pregnant women at each pregnancy.
- Procedures for documenting HBsAg results in prenatal care providers' and hospital labor and delivery records.
- Requirements for reporting HBsAg positive pregnant women's test results to the health department.
- Importance of administering hepatitis B vaccine and HBIG within 12 hours of birth, completing the 3 dose hepatitis B vaccine series by 6 months of age and conducting post-vaccination serologic testing of infants born to HBsAg positive women.

✓ **4.3.2** Encourage birthing hospitals to develop
☆ and implement a written policy to provide the first dose of hepatitis B vaccine to all newborn infants prior to discharge.

Performance Measure: Number and percent of birthing hospitals routinely administering the first dose of hepatitis B vaccine to newborn infants in the hospital as measured by a hospital policy survey conducted at least every 3 years.
Target: Set by individual programs

✓ **4.3.3** Encourage prenatal care providers to maintain and use a written protocol for testing, documenting, and informing birthing hospitals of the HBsAg status of pregnant women during each pregnancy.

Performance Measure: *Number and percent of prenatal care providers with written protocols for HBsAg testing, documenting and informing birthing hospitals as measured through a survey of Ob-Gyn practices.*
Target: *To be set by individual program.*
Performance Measure: *Percent of all pregnant women with documented maternal HBsAg status in hospital labor and delivery records.*
Target*: At least 90% of all pregnant women have documented HBsAg status in maternal record at time of delivery.*

ACTIVITIES to assure compliance with documentation and reporting procedures related to perinatal hepatitis B prevention:

✓ **4.3.4** Conduct site visits to prenatal care providers, birthing hospitals and laboratories to review and evaluate recording and reporting procedures critical to identifying HBsAg-positive women and their infants; when less-than-optimum procedures are identified, take appropriate corrective action.

Performance Measure: *Number and percentage of birthing hospitals visited*
Target: *Set by individual programs*

Performance Measure: *Percent of delivery admission records with mothers' HBsAg status recorded for the current pregnancy.*
Target: *At least 90% of all pregnant women should have documented HBsAg status in maternal records.*

Performance Measure: *Number and percent increase of prenatal care providers, birthing hospitals and laboratories with written protocols for reporting HBsAg positive pregnant women to the health department as measured through a survey of Ob-Gyn, laboratory and hospital policy surveys.*
Target*: Set by individual programs, but hospital policy survey should be conducted at least once every 3 years.*

ACTIVITIES to assure completeness of HBsAg screening of pregnant women and treatment of perinatally-exposed newborns**:**

✓ **4.3.5** Conduct on-site random sample surveys of mothers' hospital delivery records to ☆ assess completeness of HBsAg screening and documentation of maternal HBsAg ☞status.

Performance Measure: *Number and percent increase of delivery hospitals visited to conduct a hospital record review.*
Target: *Set by individual programs, but should be done at least once every 3 years.*

Intermediate Measure: *Percent increase in the number of pregnant women with HBsAg status documented appropriately in their hospital record prior to delivery*
Target: *At least 90% of all pregnant women should have documented maternal HBsAg status in charts.*

✓ **4.3.6** Assess newborns' delivery records to evaluate birthing hospitals for
☆ timely and appropriate administration of hepatitis B vaccine and/or HBIG to infants
☞ born to women with positive or unknown HBsAg test results.

Performance Measure: *Percent of infants born to women with positive or unknown HBsAg test results who receive the birth dose of hepatitis B vaccine and/or HBIG within 12 hours of birth.*
Target*:* At least 90% of all infants born to HBsAg positive women or women whose HBsAg status is unknown must receive hepatitis B vaccine and/or HBIG within 12 hours of birth.

ACTIVITIES to assure that providers complete the vaccination series of infants exposed perinatally to hepatitis B:

✓ **4.3.7** Conduct case management to ensure completion of the three dose hepatitis B
☆ vaccine series and post-vaccination serologic testing of infants born to HBsAg
☞ positive/status unknown mothers. See: *4.3.02 ELEMENTS of Perinatal Hepatitis B Case Management.*

Outcome Measure: *Percent of infants of HBsAg-positive/unknown mothers who complete the remaining two dose hepatitis B vaccine series by six to eight months of age and receive post-vaccination serologic testing by 9-15 months of age*
Target: *At least 90% of infants exposed perinatally to hepatitis B virus.*

4.3.02 ELEMENTS of Perinatal Hepatitis B Case Management:
- An active data base (preferably computerized)
- Follow-up with providers via telephone, home visits, etc.
- Follow-up with patients/families as necessary via telephone, home visits, etc.

✓ **4.3.8** Develop and maintain a database to record key information about infants born
☞ to HBsAg-positive/status unknown mothers, including the name of provider and dates of vaccination for each case. A computerized tracking system should be used for case management.

✓ **4.3.9** Follow-up with pediatric well child care providers of infants of HBsAg ☆ positive/unknown mothers as necessary to assure timely completion of the hepatitis B vaccine series and, if appropriate, post-vaccination serologic testing.

Outcome Measure: *Percent of infants of HBsAg-positive/unknown mothers who complete the remaining two dose hepatitis B vaccine series by six to eight months of age and receive post-vaccination serologic testing by 9-15 months of age*
Target: *At least 90% of infants exposed perinatally to hepatitis B virus.*

5 Service Delivery

An essential function of public health is to assure access to medical and preventive health services. For immunization programs this involves ensuring that immunization services are available on a routine basis to medically underserved persons, i.e., those who do not have a health care home where they are able to receive immunizations without significant barriers related to ability to pay, transportation, language, work hours, etc. Persons with health insurance that does not cover immunizations due to coverage exclusions or high deductibles are also considered under-served. Public health agencies have an obligation to provide immunization services for these individuals through special clinics in health departments and other public clinics or through contracts with private medical practices. Examples of immunization service delivery include mass clinics in response to VPD outbreaks as well as home visits and other field work by local health department staff to ensure appropriate immunization of high-risk persons that have been exposed to vaccine preventable diseases (including perinatal exposure to hepatitis B). In the context of public health, efforts to link underserved children, adolescents and adults with a medical home and other health and social services should also be considered an important and potentially effective immunization service.

Keywords:

Back-to-School clinics
Barriers to immunization
Case management
Co-located services
Express lane services
Field visits
Immunization clinics
"One stop shopping"
Public clinics
Reminder and recall systems
Under-served populations
Well child clinics

In 1991 the National Vaccine Advisory Committee (NVAC) cited a failure to deliver vaccines to vulnerable preschool children on schedule as the principal cause of the 1989-91 measles epidemic and advocated enhancement of the immunization delivery system to overcome barriers and eliminate missed opportunities to vaccinate. Between 1991 and 1995, immunization grant funds increased dramatically to support plans to increase immunization coverage among preschool children. Grantees directed increased funding to strengthen the public health infrastructure through improved access to public immunization services by increasing the number of clinics, expanding clinic hours, and improving the quality of public immunization services. Over the past several years the growth of Medicaid managed care, the success of the Vaccines for Children Program (VFC) and the introduction of the Children's Health Insurance Program (CHIP) have served to dramatically reduce the number of children who rely on the delivery of immunization services by the public sector. Concurrently, in most states the role of public health in delivering immunization services has diminished substantially along with the level of federal grant funding available to support service delivery functions. As a result, many immunization programs are now faced with the challenge of determining an appropriate level of direct immunization services to ensure access by individuals who are unable to be served in a health care home.

References:

- 2001 VFC Program Operations Guide (CDC)
- *Standards for Pediatric and Adolescent Immunization Practices* -Draft (CDC) (CD Rom 2001 Immunization Works)
- *Standards for Adult Immunization Practices*- Draft (CDC) (CD Rom 2001 Immunization Works).
- ACIP Recommendations: General Immunization, Adolescent Immunization, Adult Immunization and Vaccine-Specific Recommendations (CDC) (CD Rom 2001 Immunization Works)
- WIC Policy Memorandum (USDA) (Appendix:1)
- *Evaluating the Utilization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs* (available from DTQ1@CDC.GOV beginning August, 2001)
- The Measles Epidemic, The Problems, Barriers, and Recommendations (NVAC), JAMA, September 18, 1991, Vol 266, No. 11)

ACTIVITY AREAS

5.1 Underserved Populations
5.2 Medical Home Promotion

5.1 UNDERSERVED POPULATIONS

5.1.0 DEFINITION of underserved populations:
Underserved populations include persons of all ages – children, adolescents and adults -- who do not have a health care home where they are able to receive immunizations without significant barriers related to ability to pay, transportation, language, work hours, etc. Persons with health insurance that does not cover immunizations due to coverage exclusions or high deductibles are considered underserved.

ACTIVITIES to ensure that medically underserved children, adolescents and adults have access to immunization services:

☆ ✓ ☞ **5.1.1** Ensure that immunization services are available for underserved populations of all age groups in every county and major city through public clinics i.e., health departments, community health centers, county/municipal hospital outpatient clinics, senior centers, and contracts or other arrangements with the private sector.

Performance Measure: *Number [increase] of public clinics providing immunization services to the underserved, by age group and location*
Target: *Set by individual program*

✓ **5.1.2** Provide ACIP-recommended vaccines in public well child and pediatric primary care clinics, as necessary.

Performance Measure: *Number of public well child and pediatric primary care clinics providing immunization services*
Target: *100%*

☆ ✓ **5.1.3** Support "back-to-school" clinics and other special efforts by health department and school health staff to provide immunization services for children who are not up-to-date at entry to school or day care to ensure these children are brought up-to-date or are granted exemption from one or more immunizations according to individual state law or rules. Where appropriate, support such as additional vaccine and informational materials should be provided to the private sector to ensure that children entering school are able to receive recommended vaccines in their health care homes.

☆ ✓ **5.1.4** Ensure that immunization services are readily accessible to underserved populations of all ages.

Performance Measure: *In areas where there is a demonstrated a need for after-hours immunization services, the number and percent [increase] of public clinics providing <u>additional</u> immunization services outside of routine clinic hours*

Target: *Set by individual program*

☆ ✓ ☞ **5.1.5** Co-locate public immunization services with other public health or social service agencies that serve persons likely to be at high risk for under-immunization (e.g., WIC sites and Medicaid providers, Medicare, SCHIP and TANF enrollment offices) to facilitate linkage with the services provided by these agencies and provide "one-stop shopping" for recipients.

ACTIVITIES to identify under immunized children and adolescents and to ensure they receive ACIP-recommended immunizations:

☆ ✓ ☞ **5.1.6** Conduct annual surveys of public and private schools to identify children who are not up-to-date at entry to Kindergarten, first grade, and/or key intermediate grade(s) to ensure under immunized children are brought up to date (or are determined to be exempt from one or more immunizations), and ensure follow-up of these individuals to ensure they are brought up to date. Consider moving this assessment.

Performance Measure: *Post-survey vaccination coverage levels (after program follow-up) for vaccines required for entry into school and day care, by vaccine antigen and type of facility*
Target: *Set by individual programs, but at least 95%*

☆ ✓ ☞ **5.1.7** Conduct annual surveys of day care facilities to identify children who are not up-to-date at admission to ensure under immunized children are brought up to date (or determined to be exempt from one or more immunizations), and follow-up with these individuals to ensure they are brought up to date.

Performance Measure: *Post-survey vaccination coverage levels (after program follow-up) for vaccines required for entry into school and day care, by vaccine antigen and type of facility*
Target: *Set by individual programs, but at least 95%*

☆ ✓ ☞ **5.1.8** Coordinate activities with state/local WIC offices to assure that children participating in WIC are screened, either onsite or via appropriate referrals, in accordance with USDA Policy Memorandum. At a minimum, screening should include a review of specific marker antigens at defined age points as specified in USDA Memorandum (Appendix 1). Information on the number of sites, the number of individuals served and the methods and level of involvement with immunization-related activities should be collected and maintained.

Performance Measure: *Percent of children in WIC screened for immunization status at one or more WIC visits*

Target: *100%*

Outcome Measure: *Percent up-to-date at visit*
Target: *90%*

ACTIVITIES to ensure that underserved high-risk children, adolescents and adults (those belonging to groups known to be at high risk for under immunization or exposure to VPDs) receive ACIP-recommended immunizations:

✓ **5.1.9** Evaluate the level of VFC enrollment program-wide and in areas known to have large underserved populations.

Performance Measure: *Percent of immunization providers who are enrolled in the VFC Program*
Target*: Set by individual programs*

Performance Measure: *Percent of Medicaid immunization providers who are enrolled in the VFC Program*
Target: *Set by individual programs, but at least 90%*

☆ ✓ **5.1.10** Follow-up as necessary with the families of infants born to women with positive or unknown HBsAg status to ensure that their exposed infants and household contacts complete the hepatitis B vaccine series and, receive if appropriate, post-vaccination serologic testing on a timely basis. *See Chapter 4.3 Perinatal Hepatitis B Prevention.*

Performance Measure: *Percent [increase] of infants and susceptible household and sexual contacts of HBsAg-positive pregnant women who complete the three dose hepatitis B vaccine series*
Target: *Annual improvement toward 90% set by individual programs*

☆ ✓ **5.1.11** In areas identified as pockets of need because of low coverage levels (or surrogate indicators for low coverage) collaborate with community-based organizations (e.g., churches, schools, child care facilities, homeless shelters, advocacy groups) to identify, refer and follow-up underserved and high-risk infants, children, adolescents and adults in need of immunizations.

Performance Measure: *Number [increase] of children, adolescents and/or adults identified by community-based organizations as needing immunizations*

Target: *Set by individual program*

☆ **5.1.12** Collaborate with other state and federal agencies (e.g., WIC, FQHCs,
✓ Medicaid, Medicare, TANF) to identify, refer and follow-up underserved and high-risk infants, children, adolescents and adults in need of immunizations.

Performance Measure: *Number of children, adolescents and/or adults identified by other agencies as needing and subsequently receiving immunizations*
Target: *Set by individual program*

☆ **5.1.13** Collaborate with WIC to refer under immunized WIC enrollees to an
✓ appropriate public clinic or medical home.

Performance Measure: *Percent referred for immunizations by WIC*
Target: *100%*

☆ **5.1.14** Implement effective reminder and recall efforts in all public clinics that provide
✓ immunization services. Reminder/recall systems should apply to adults and
☞ adolescents as well as children.

Performance Measure: *Number and percent [increase] of public clinics actively using reminder and recall systems, by type of reminder (telephone, mail, etc.)*
Target: *Set by individual program*

☆ **5.1.15** Collaborate with public clinics and treatment centers, including HIV counseling centers, intravenous drug use clinics, STD clinics, correctional and detention centers, etc., to provide hepatitis B vaccine to adolescents at high risk for hepatitis B.

Performance measure: *Number [increase] of facilities providing hepatitis B vaccine, by type of program*
Target: *Set by individual program*

☆ **5.1.16** Establish collaborative outreach efforts between public clinics and community organizations to contact and provide immunizations to "hard-to-reach" individuals who fail to respond to recall messages.

Performance Measure: *Number and percent of public clinics that have instituted patient outreach efforts in collaboration with community groups and the private medical community*
Target: *Set by individual program*

5.1.17 Encourage local health departments to enroll as Medicare providers to foster immunization of adults in the public sector.

5.2. MEDICAL HOME PROMOTION

ACTIVITIES to ensure that all children, adolescents and adults utilize a medical home to facilitate continuity of care, including receipt of all recommended immunizations in a comprehensive care setting:

✓ **5.2.1** Identify the health care homes of children, adolescents and adults receiving immunization services in public clinics and, when appropriate, refer them to their health care homes for future immunizations. *See Evaluating the Utilization of Health Department Immunization-only Clinics: A Toolkit for Immunization Programs* (available from DTQ1@CDC.GOV beginning August, 2001).

5.2.2 Arrange a health care home for public clinic clients that lack one.

5.2.3 Refer children and adolescents receiving immunization services in public clinics to Medicaid, SCHIP and/or WIC if they are potentially eligible.

> ***Performance Measure:*** *Number and percent of children and adolescents referred to Medicaid, to SCHIP, and to WIC*
> ***Target(s):*** *Set by individual program*

5.2.4 Refer to Medicare all persons 65+ years of age who are Medicare eligible to ensure Pneumococcal and influenza immunizations at no charge.

✓ **5.2.5** Enroll into the VFC Program providers (including all FQHCs and local health departments) that serve Medicaid-eligible, uninsured and American Indian/Alaska Native patients.

> ***Performance Measure:*** *Number and percent [increase] of child and adolescent immunization providers both public and private enrolled in VFC program*
> ***Target:*** *100%*

✓ **5.2.6** Increase recruitment of private providers into the VFC Program by promoting the VFC program in special mailings, newsletters, program web-sites, e-mail list-serves and similar communication networks of private provider organizations (e.g., AAP, AAFP, ACP) and managed care organizations.

> ***Performance Measure:*** *Number and percent of public and private providers of immunization enrolled in VFC; total by provider type (public clinic, family physician, and pediatrician)*
> **Target:** *Set by individual program*

6 Consumer Information

Keywords:
Consumer
Community-Based Organizations
Immunization Promotion Hotlines
Educational Materials
Health Education
Media Campaigns
National Vaccine Injury Compensation Program (VICP)
Public Awareness
Risk-Benefit Communication
Vaccine Information Statements (VIS)

Every immunization program should include efforts to inform, influence and motivate lay audiences of all ages about the importance of immunizations. Historically, these activities have included dissemination of technical information through distribution of materials such as Vaccine Information Statements (VIS), fact sheets and brochures. In addition, broader promotional efforts through various mass media can be used to raise public awareness to a level that encourages individuals to visit a health care provider to obtain one or more vaccines or to seek more in-depth knowledge about immunizations. Immunization programs that develop positive relationships with the local media are often able to achieve communication of well-timed messages to the public about specific immunization issues.

Communication with immunization "consumers" can be undertaken by immunization program staff directly but are sometimes more effective when done in collaboration with community leaders, advocacy groups and organizations such as churches, schools, civic clubs, businesses, and other special interest groups. The role and responsibility of medical providers in educating their patients about immunizations must not be overlooked. All communication efforts should address identified needs for information on the part of individuals and specific groups and should be directed toward improving knowledge, attitudes, and ultimately, immunization-seeking behavior.

References:

- Vaccine Information Statements (CDC) (CD Rom 2001 Immunization Works)
- *Standards for Pediatric and Adolescent Immunization Practices* (CDC) (CDC Rom 2001 Immunization Works)
- Standards for Adult Immunization Practices Draft (CDC) (CD Rom 2001 Immunization Works)
- National Vaccine Injury Compensation Program (VICP) website http://bhpr.hrsa.gov/vicp/vicp.htm

ACTIVITY AREAS

6.1 Information Development and Dissemination
6.2 Vaccine Benefit and Risk Communication

6.1 INFORMATION DEVELOPMENT AND DISSEMINATION

ACTIVITIES to inform consumers about vaccine preventable diseases and vaccines to prevent them, through direct communication:

6.1.01 ELEMENTS of an effective consumer information program:

- Determination of the information and education needs for general public and targeted consumer advocacy groups
- Involvement of target audiences in decisions on and production of materials to ensure that written and verbal information is relevant, culturally sensitive, linguistically appropriate, useable and 'owned' by target audiences
- Pre-testing of materials to make sure products are clear, relevant and appealing; and
- Evaluation of the impact of the materials

✓ **6.1.1** Ensure that people of all ages are provided general and specific immunization information in accordance with the program's over-all strategy to assure immunizations for all age groups. *See Chapter 1.1 Program Planning* and *6.1.01 ELEMENTS of an effective consumer information program*.

✓ **6.1.2** Update the official program immunization record card ("shot card") whenever new vaccines are recommended by the ACIP.

✓ **6.1.3** Ensure that messages to consumers are relevant, accurate, appropriate and useful. *See 6.1.01 ELEMENTS of an effective consumer information program and 6.1. 02 WHAT CONSUMERS NEED TO KNOW to seek and accept immunizations.*

6.1.02 WHAT CONSUMERS NEED TO KNOW to seek and accept immunizations

- Information about VPDs
- Vaccines are safe and effective
- Immunization recommendations for their age group (or their child)
- Location of facilities providing immunizations for underserved and under-insured populations
- Where to get immunization information (e.g., hot-line numbers and web sites)
- Responsibility to maintain an immunization record and bring it to all provider visits

6.1.4 Assign one or more persons responsibility for gathering, developing and disseminating immunization-related information and materials and include these responsibilities in written job description(s).

6.1.5 Implement procedures to respond to inquiries (telephone, FAX, etc.) about vaccine preventable diseases, vaccines, clinic sites and hours for vaccinations, and other immunization-related concerns.

6.1.6 Provide media with updates on vaccine preventable diseases, new vaccines, targeted "at-risk" populations, immunization recommendations and schedules, planned immunization activities, and information on evidence-based immunization interventions such as child, adolescent and adult sub-population laws/regulations and standing orders.

Performance measure: *Number of updates provided proactively to media, by topic*
Target: *Set by individual program*

6.1.7 Promote hepatitis B vaccination for all children born after 9/30/83 to mothers born in countries with chronic hepatitis B virus infection rates of two percent or higher (Asia, Africa, and northern South America).

ACTIVITIES to improve the quality of program communications with consumers:

6.1.8 Develop written procedures for responding to inquiries from the public.

✓ **6.1.9** Maintain a Consumer Inquiry Log to document consumer questions from telephone, FAX, hot line, and other sources of inquiry about vaccines and vaccination issues such as vaccine safety, side effects, etc. Use this information to identify patterns and trends related to consumer concerns and perceptions about immunization.

ACTIVITIES to enhance consumer education through collaboration with community leaders, advocacy groups, legislators, and other special interest groups:

6.1.10 Provide consumer and advocacy groups, legislators, and special interest groups with information on vaccine preventable diseases, new vaccines, targeted "at-risk" populations, planned immunization activities, and information on recommendations and requirements for immunization of children, adolescents and adults.

Performance measure: *Number [increase] of immunization informational packets provided to consumer groups annually*
Target: *Set by individual program*

6.1.11 Collaborate with consumer and advocacy groups to develop and disseminate consumer information about vaccines for targeted high risk groups recommended to receive influenza and Pneumococcal immunizations.

✓ **6.1.12** Promote use of a patient/parent-held immunization record card, and the need to bring the card to every medical visit through collaboration with consumer advocacy

groups and professional associations. All providers not using the official record card should be reminded of the need to revise their own cards whenever new vaccines are recommended by the ACIP. *See Chapter 4. Provider Quality Assurance*.

ACTIVITIES to enhance education of high-risk individuals through collaboration with health care providers:

✓ **6.1.13** Where appropriate, collaborate with tribal clinics, IHS area offices and service units, and other entities that provide medical services to American Indians and Alaska Natives in the development and dissemination of materials about immunizations targeted to Native populations. Emphasis should be place on VPDs such as hepatitis A and hepatitis B for which Native populations are at increased risk.

✓ **6.1.14** Collaborate with public clinics and treatment centers, including HIV counseling centers, intravenous drug use clinics, STD clinics, correctional and juvenile detention centers, etc., in the development and dissemination of consumer materials targeted to adolescents and adults at high risk for hepatitis B.

> ***Performance measure:*** *Number [increase] of specific program types collaborated with and number of informational products developed*
> ***Target:*** *Set by individual program*

6.1.15 Collaborate with hospitals, health maintenance organizations, health insurance companies, and professional organizations in their development of immunization information and education materials for distribution to their patients.

6.2 VACCINE BENEFIT and RISK COMMUNICATION

ACTIVITIES to ensure consumer knowledge and understanding of the benefits and risks of vaccines, and of the National Vaccine Injury Compensation Program:

For additional activities, refer to *Chapter 4.2 Provider Education* and *Chapter 7.4 Vaccine Safety.*

✓ **6.2.1** Reinforce to all providers their responsibility to ensure clients are aware of the ☞ National Vaccine Injury Compensation Program (VICP).

6.2.2 Ensure that the current CDC materials on vaccines and their benefits and risks such as fact sheets and Question/Answer sheets are quickly and widely distributed to media, consumer groups and providers through articles and web sites.

> ***Performance measure:*** *Percent of new informational materials on vaccine benefits and risks provided to media, consumer advocacy and provider groups within one month of receipt from CDC*
> ***Target:*** *Set by individual program*

✓ **6.2.3** Ensure new and/or revised Vaccine Information Statements (VIS) is quickly ☞ distributed to providers so clients will be provided with the most current information. Ensure that providers are aware that VIS is available in other languages and the means of obtaining those VIS.

> ***Performance measure:*** *Percent of new and/or revised VIS distributed to providers within one month of receipt from CDC*
> ***Target:*** *Set by individual program*

7 Surveillance

Effective Vaccine Preventable Disease (VPD) surveillance at national, state and local levels serves to document the impact of vaccination programs, evaluate the effectiveness of current vaccines and vaccination policies, and identify needed changes in program strategies. It also monitors progress toward disease reduction and elimination goals and serves to signal the need for public health responses.

Surveillance is used to evaluate the impact of changes in immunization policies such as the introduction of acellular pertussis vaccines for use in infants and the use of the all-IPV schedule for the prevention of poliomyelitis. Surveillance is especially critical following the introduction of a new vaccine to monitor post-licensure vaccine safety, coverage and decline in disease. For other diseases such as hepatitis B, surveillance may rely heavily on laboratory screening of high risk populations and reporting of chronically infected persons as steps in preventing transmission.

Keywords:
Active and passive surveillance
Adverse events
Case definition
Case investigation
Council of State and Territorial Epidemiologists (CSTE)
Disease reporting
HBsAg Screening
Laboratory reporting
Morbidity and mortality
National Childhood Vaccine Injury Act
National Electronic Disease Surveillance System (NEDSS)
National Electronic Telecommunications System for Surveillance (NETSS)
Sentinel sites
Vaccine Adverse Events Reporting System (VAERS)
Vaccine Preventable Diseases (VPDs)

The Council of State and Territorial Epidemiologists (CSTE) has the responsibility to decide what diseases should be reported nationally. Priority areas of concern for CSTE are surveillance and epidemiology of infectious diseases, chronic diseases and conditions, and environmental health concerns. CSTE promotes the effective use of epidemiologic data to guide public health practices and improve health. This is accomplished by supporting the use of effective public health surveillance and good epidemiologic practice through training, capacity development, peer consultation, developing standards for practice, and advocating for resources and scientifically based policy.

The role of immunization programs in VPD surveillance varies considerably from state to state, with many immunization programs sharing this responsibility to a greater or lesser degree with other organizational sections, branches, or divisions responsible for general communicable disease control or epidemiology. However, to meet the national disease elimination objectives established for VPD surveillance, activities will need to be intensified and enhanced. With many VPDs at all time low levels, the involvement of immunization program management and staff will be essential to assure complete case identification and thorough case investigation.

The success of immunization programs in reducing vaccine-preventable diseases to record low levels has given rise to increased concerns about vaccine safety. Monitoring adverse events and addressing vaccine safety concerns is an essential part of an immunization program. The National Childhood Vaccine Injury Act of 1986 mandated the reporting of certain adverse events following immunization. This Act led to the establishment of the Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting system for adverse events following receipt of any U.S. licensed vaccine. VAERS is operated jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is the cornerstone of a comprehensive vaccine safety monitoring program to maintain public confidence in vaccines and vaccination programs.

Public and private immunization programs perform a critical role in vaccine safety by ensuring that their providers report suspected adverse events following vaccination through VAERS. By collating and analyzing VAERS nationwide, CDC is able to identify and respond to vaccine-associated risks potentially not identified in pre-licensure assessments. In addition, VAERS can detect unusual increases in recognized events, vaccine lots with unusual numbers or types of reported events, and, by collecting and following up additional case information, may detect pre-existing conditions that may be contraindications to vaccination. Results of VAERS analyses are used to trigger investigations of hypothesized relationships between a vaccine and adverse events.

VAERS data are available via the VAERS web site (see below). Routine updates and/or custom searches are available to grantees on request from the VAERS program. Adverse events designated as serious require additional follow-up by the VAERS program to obtain more complete medical information with which to evaluate the case. These and other enhancements to CDC's vaccine safety efforts will add to the knowledge regarding vaccine safety and help maintain confidence in our vaccination programs.

Currently the National Childhood Vaccine Injury Act specifies vaccines/toxoids and types of events that must be reported. However, health care providers are encouraged to report all clinically significant events to VAERS. Reporting forms and instructions are available from the VAERS web site (www.vaers.org), or by calling 1-800-822-7967, or sending an e-mail to info@vaers.org.

To modernize and enhance public health surveillance and information systems, CDC and its public health partners are implementing the National Electronic Disease Surveillance System (NEDSS). CDC's NEDSS implementation strategies include ensuring that the relevant activities of state and local immunization programs are consistent with the functional and technical specifications of the NEDSS information architecture. State and local immunization programs should evaluate current activities with respect to the NEDSS information systems architecture and begin to modify these activities, if necessary, so that they are consistent with NEDSS specifications.

Information describing these specifications can be found on the internet at http://www.cdc.gov/od/hissb/docs/NEDSSSysArcht1.pdf

ACTIVITY AREAS

7.1 Disease Surveillance and Response
7.2 VPD Reporting
7.3 Perinatal Hepatitis B Screening
7.4. Vaccine Safety

References:

- Manual for the Surveillance of Vaccine Preventable Diseases, (CDC)
- Healthy People 2010 National Objectives, (DHHS)
- Morbidity and Mortality Weekly Report (CDC) website: (www.cdc.gov/mmwr/)
- Standards for Pediatric, Adolescent Immunization Practices (NVAC)
- Standards for Adult Immunization Practices (NVAC)
- Managing a Hepatitis B Prevention Program: A Guide to Life as a Program Coordinator (CDC)
- Hepatitis Surveillance Report (CDC NCID DVRD Hepatitis Branch, Report No. 56, April 1995.36 p.)
- CSTE web site (www.cste.org)
- VAERS web site (www.vaers.org)
- NEDSS web site (www.cdc.gov/od/hissb/docs/NEDSSSysArcht1.pdf)

7.1 DISEASE SURVEILLANCE AND RESPONSE

For additional details, refer to the Manual for Surveillance of Vaccine-Preventable Diseases.

ACTIVITIES to establish, enhance, and maintain a system to identify and investigate cases and control outbreaks of VPDs:

7.1.0 ELEMENTS of a VPD surveillance and response system:

- Active and/or passive surveillance
- Sentinel reporting sites
- Laboratory reporting
- Case finding techniques
- Systematic collection of reports on suspected cases
- Investigation of suspected cases
- Interpretation of case reports
- Outbreak control activities

✓ **7.1.1** Develop administrative policies and procedures to assure the systematic, institutionalized reporting of cases and suspected cases of VPDs by providers, health care institutions, and laboratories.

✓ **7.1.2** Obtain the authority for health department staff to review medical records of persons who are cases or suspected cases of all VPDs.

✓ **7.1.3** Ensure availability of written up-to-date guidelines for case investigation, outbreak investigation**,** and outbreak control of all VPDs.

✓ **7.1.4** Ensure that health department staff responsible for VPD surveillance and response is trained to perform VPD case and suspect case investigations, outbreak investigations**,** and outbreak control.

✓ **7.1.5** Initiate VPD case investigations and outbreak investigations promptly and complete outbreak control measures in a timely manner.

✓ **7.1.6** Develop and distribute written up-to-date laboratory guidelines for each VPD detailing the appropriate clinical specimens to obtain, recommended laboratory tests and laboratories, specimen handling, and expected time lines for laboratory results.

✓ **7.1.7** Ensure that clinics, schools, day care facilities, hospitals and other VPD sentinel sites routinely submit surveillance reports to health departments.

✓ **7.1.8** Conduct enhanced, active surveillance in communities where a VPD is prevalent.

7.1.9 Pursue unreported cases of VPDs by searching laboratory, hospital and/or death certificate data.

✓ **7.1.10** Ensure that procedures exist and are followed for entering and analyzing surveillance, investigation and outbreak data in a timely fashion.

✓ **7.1.11** Analyze, review and interpret surveillance data regularly, and outbreak data as needed.

✓ **7.1.12** Monitor the quality of VPD surveillance by reviewing surveillance indicators, problems identified, and strategies developed and implemented to address them.

✓ **7.1.13** Ensure feedback of surveillance data to case reporters, institutions involved and all other surveillance participants.

Congenital Rubella Syndrome (CRS)

✓ **7.1.14** Investigate each suspected case of CRS. Collect demographic information,
☞ maternal history (complete vaccination information, prior pregnancies, and country of these births/pregnancies, previous laboratory testing, country of birth and clinical symptoms during pregnancy), infant's clinical details (e.g., cataracts, hearing impairment, developmental delay, type of congenital heart defect, meningoencephalitis, microcephaly), and laboratory tests and results for both mother and child including infant IgM. Obtain clinical specimens for rubella virus isolation (e.g., pharyngeal swabs) from all probable and confirmed cases of Congenital Rubella Syndrome.

Diphtheria

✓ **7.1.15** Investigate each suspected case of diphtheria. Collect demographic data,
☞ complete vaccination information, travel information, specimens for diagnostics, details of clinical syndrome, treatment, and outcome**.** Investigate household and other close contacts; collect specimen for culture at time of initial investigation.

Haemophilus influenzae

✓ **7.1.16** Investigate cases of *Haemophilus influenzae* invasive disease among children
☞ <15 years of age. Promote laboratory reporting of cases. Collect demographic data, complete vaccination information (date, manufacturer, lot number), type of clinical syndrome (meningitis, bacteremia, pneumonia), and outcome, specimen sources (CSF, blood, joint fluid) and isolate serotype.

Performance Measure: *The proportion of Haemophilus influenzae invasive disease cases among children <5 years of age with vaccination information complete (dose number, date, manufacturer, lot number)*
Target: *95%*

Performance Measure: *The proportion of Haemophilus influenzae isolates from cases <5 years of age that were serotype*
Target: 95%

Hepatitis A

✓ **7.1.17** Investigate reported cases to confirm diagnosis, identify risk factors for ☞ transmission, identify missed opportunities for vaccination, and assure administration of post-exposure prophylaxis to contacts at risk. Assure laboratory reporting of IgM anti-HAV positive results to health department.

Hepatitis B

✓ **7.1.18** Investigate reported cases to confirm diagnosis, identify risk factors for ☞ transmission, identify missed opportunities for vaccination, assure appropriate counseling, refer for medical management, and ensure post-exposure prophylaxis of household and sexual contacts of HBsAg positive women. *See Chapter 7.3 Perinatal Hepatitis B Screening*. *Also see Chapter 4: Perinatal Hepatitis B Prevention*

✓ **7.1.19** Assure that laboratories report all HBsAg-positive and IgM anti-HBc-positive test results to the health department.

✓ **7.1.20** Assure immediate reporting of HBsAg-positive results in pregnant women by prenatal care providers and birthing hospitals and health department collaboration in tracking infants of HBsAg women.

Performance Measure: % of HBsAg positive pregnant women reported to the health department.
Target: At least 90% of expected births to HBsAg positive pregnant women.

✓ **7.1.21** Maintain a registry of persons with HBsAg-positive results.

Influenza

✓ **7.1.22** Collaborate with state/local influenza surveillance coordinators in developing plans for timely and coordinated dissemination of influenza vaccination promotions. Also ensure that state and local influenza virus surveillance data is disseminated to providers and the public during each influenza season.

Measles

✓ **7.1.23** Investigate suspected case of measles promptly; for each case, collect ☞ demographic information, complete vaccination information, transmission setting, source of exposure, clinical symptoms, and laboratory findings.

Performance Measure: *The proportion of measles cases for which measles vaccination status is obtained*
Target: *100%*

Performance Measure: *The proportion of measles cases or chains of transmission with an imported source*
Target: *100%*

✓ **7.1.24** Obtain laboratory confirmation of measles cases, preferably by capture IgM assay. Collect specimens (urine or nasopharyngeal swabs) for virus isolation and typing from every probable or confirmed measles case at the time of initial evaluation (no later than seven days following rash onset); in larger outbreaks, specimens are collected from four or more cases.

Performance Measure: *The proportion of measles cases that are laboratory confirmed*
Target: *95%*

Performance Measure: *The proportion of measles cases or chains of transmission for which a specimen for virus isolation is collected and sent to CDC*
Target: *95%*

Mumps

✓ **7.1.25** Investigate suspected cases of mumps promptly; collect demographic ☞ background, complete vaccination information, transmission setting, source of exposure, clinical symptoms and outcome, clinical specimens and laboratory findings. A mumps serology (IgM) should be collected on all suspected cases.

Performance Measure: *The proportion of suspected cases of mumps for which appropriate clinical specimens were obtained and submitted to the laboratory*
Target: *Set by individual program; progress toward 90%*

Performance Measure: *The proportion of confirmed and probable cases for which complete vaccination status is known*
Target: *Set by individual program; progress toward 90%*

Pertussis

✓ **1.26** Investigate suspected cases of pertussis promptly. For all cases of children ☞ <10 years of age collect transmission setting, source of exposure, clinical symptoms and outcome, and results of nasopharyngeal specimen cultures. For adolescents and adults, collect demographic background, dates of each vaccination, type of vaccine (DPT or DTaP), lot number, and manufacturer. Investigate household and other close contacts of cases; collect and submit nasopharyngeal specimens at time of initial evaluation.

Performance Measure: *The proportion of suspected cases from which clinical specimens are obtained*
Target: *>90 %*

Performance Measure: *The proportion of pertussis cases meeting the clinical case definition that are culture-confirmed*
Target: *Set by individual program, but at least 60%*

Performance Measure: *The proportion of cases confirmed by isolation of B pertussis by culture*
Target: *Set by individual program, but at least 30%*

Performance Measure: *The proportion of probable and confirmed pertussis cases among children <10 years of age for which a vaccination history was completed, including type of vaccine and lot number for each dose*
Target: *90%*

Polio

✓☞ **7.1.27** Investigate promptly cases of acute flaccid paralysis. Collect demographic background, complete vaccination information (dates of each vaccination, type of vaccine and lot #), transmission setting, source of exposure, clinical symptoms and outcome, and laboratory findings; obtain, properly transport and process stool specimens for virus isolation.

Pneumococcal Invasive Disease

✓☞ **7.1.28** Investigate all cases of invasive Pneumococcal disease among children <5 years of age (e.g. serotype, antibiotic resistance).

Performance Measure: *The proportion of Pneumococcal invasive disease cases among children <5 years of age for whom complete vaccination information (type, date, manufacturer, lot number) was collected*
Target: *Set by individual program; progress toward 95%*

Performance Measure: *The proportions of Pneumococcal isolates from cases of invasive disease <5 years of age that are serotype and checked for antibiotic resistance*
Target: *Set by individual program; progress toward 100%*

7.1.29 Identify possible failures of vaccine in children <5 who received at least one dose of Pneumococcal conjugate vaccine and have Pneumococcal infection (i.e., cases where Streptococcus pneumoniae is isolated from a normally sterile site such as blood or CSF). In cases where these criteria are met, isolates should be sent to CDC through the state laboratory with a completed tracking form. (Forms can be obtained by calling the CDC Respiratory Diseases Branch at 404-639-2215.)

***Performance measure**: Number and percent of vaccine failures meeting the criteria*
***Target:** Set by individual programs*

Rubella

✓ **7.1.30** Investigate suspected cases of rubella; collect demographic information, ☞ country of origin, complete vaccination information, transmission setting, source of exposure, clinical symptoms, and laboratory findings (e.g., rubella IgM antibody or paired sera for rubella IgG), and for women, pregnancy status and, if pregnant, outcome of pregnancy; obtain clinical specimens for rubella virus isolation (e.g., pharyngeal swabs) from all probable and confirmed cases of rubella. In outbreak settings, obtain clinical specimens from three to four cases for viral isolation.

***Performance Measure:** The proportion of confirmed rubella cases among women of child-bearing age with known pregnancy status*
***Target:** 100 %*

***Performance Measure:** The proportion of confirmed rubella cases that are laboratory confirmed*
***Target:** 95%*

✓ **7.1.31** Assure prenatal screening of all pregnant women for rubella antibody, and documentation of results in provider and birthing hospital chart.

***Performance Measure:** Number and percent of pregnant women with documentation of rubella status in pre-delivery hospital record*
***Target:** Set by individual program; progress toward 100%*

✓ **7.1.32** Assure rubella antibody-negative mothers are made aware of benefits and risks of rubella vaccine, offered rubella vaccine following delivery, and acceptors receive the vaccine before hospital discharge.

***Performance Measure:** Number and percent of rubella antibody-negative pregnant women receiving rubella vaccine following delivery and prior to discharge*
***Target:** Set by individual program; progress toward 100%*

Tetanus

✓ **7.1.33** Ensure the investigation of reported cases of tetanus; collect demographic ☞ and vaccination history for all recommended vaccines, predisposing conditions (e.g., IV drug use, body piercing, tattoo) including a history of wound or injury, clinical symptoms and outcome.

Varicella

✓ **7.1.34** Encourage providers, schools, and others to report all cases of varicella to the health department with age, varicella vaccination history, and severity of disease data. Severity of disease is categorized as mild (<50 lesions, in which case the lesions can be counted within 30 seconds), severe (>500 lesions, in which case the lesions are

clumped so closely together one can hardly see normal skin), and moderate (anything between mild and severe).

Performance Measure: *Number and annual percent decline of reported cases by age groups*
Target: *Set by individual program; progress towards 90%*

✓ **7.1.35** Investigate reports of varicella-related deaths. Collect demographic and ☞ complete vaccination information, transmission setting, source of exposure, and clinical symptoms and outcome.

✓ **7.1.36** Investigate varicella outbreaks occurring in schools, child care and institutional facilities, and offer control efforts either through provision of vaccine in public clinics or by referrals to primary health care providers. In outbreak settings, obtain clinical specimens from at least one case for verification of varicella virus.

7.2 VPD REPORTING

ACTIVITIES to measure VPD morbidity and mortality, and evaluate the impact of new vaccines and immunization policies:

✓ **7.2.1** Complete and transmit both case reports and supplemental surveillance ☞ information to CDC on appropriate CDC forms by mail or via NETSS. Completed CDC form/NETSS screen due to CDC within one month of diagnosis of all reported cases of measles, pertussis, congenital rubella, and rubella, and cases of invasive Hib and invasive Pneumococcal disease in children less than five years old.

Performance Measure: *Percent of case reports for disease submitted to CDC within one month of diagnosis*
Performance Measure: *Percent of cases requiring supplemental surveillance information submitted to CDC*
Targets: *90%*

✓ **7.2.2** Disseminate surveillance morbidity and mortality data regularly to network participants, providers, policy makers, and the public.

Congenital Rubella Syndrome (CRS)

✓ **7.2.3** Report to CDC all cases of CRS on form CDC 71-17 Rev 3-95.
☞

Performance Measure: *Proportion of CRS cases for which the completed case report or NETSS screen were submitted within one month of diagnosis or receipt of case report*
Target: *100%*

Diphtheria

✓ **7.2.4** Report results of initial investigation of suspected cases to CDC by telephone ☞ immediately.

Haemophilus influenzae

✓ **7.2.5** Report each confirmed case of *Haemophilus influenzae* invasive disease in ☞ children <15 years of age to CDC and submit supplemental surveillance information within one month of diagnosis including serotype via NETSS or by using the National Bacterial Meningitis and Bacteremia Case Report form (CDC 52.15 Rev 02-93).

Performance Measure: *Proportion of cases of Haemophilus influenzae invasive disease in people <15 years of age for which a completed case or NETSS extended report was submitted within one month of diagnosis*
Target: *100%*

Hepatitis A

✓ **7.2.6** If applicable, report each confirmed case of Hepatitis A among persons <19 ☞ years of age to CDC via NETSS or using the Viral Hepatitis Case Report form (CDC 53.1 Rev 6-93).

Performance Measure: *Proportion of acute cases of hepatitis A among people <19 years of age for which a Viral Hepatitis Case Report (CDC Form 53.1) or NETSS extended record for hepatitis was submitted*
Target: *100%*

Hepatitis B

✓ **7.2.7** Report each confirmed case of Hepatitis B among persons <19 years of age to ☞ CDC via NETSS or using the Viral Hepatitis Case Report form (CDC 53.1 Rev 6-93).

Performance Measure: *Proportion of acute cases of hepatitis B among people <19 years of age for which a Viral Hepatitis Case Report (CDC Form 53.1) or NETSS extended record for hepatitis was submitted*
Target: *100%*

Measles

✓ **7.2.8** Report each confirmed case of measles to CDC by telephone or FAX and ☞ submit supplemental surveillance information within one month of diagnosis via NETSS or the Measles Case Worksheet.

Performance Measure: *Proportion of confirmed measles cases for which a completed case report was submitted by mail or NETSS within one month of diagnosis*
Target: *100%*

✓ **7.2.9** Collect and submit to CDC quarterly the number of discarded measles cases ☞ which do and do not meet the case definition**.** Report is due within 30 days of the close of each quarter.

Mumps

✓ **7.2.10** Report each confirmed case of mumps to CDC via NETSS, telephone or FAX.
☞

Pertussis

✓ **7.2.11** Report each probable or confirmed case of pertussis to CDC and submit ☞ supplemental surveillance information within one month of diagnosis via NETSS or using the pertussis case report form (CDC 71.14A Rev 6-68).

Performance Measure: *Proportion of pertussis cases for which the completed case report or NETSS screen were submitted within one month of diagnosis*
Target: *100%*

Pneumococcal Invasive Disease

✓ **7.2.12** Report each confirmed case of invasive Pneumococcal disease in children ☞less than 5 years of age to CDC and submit supplemental surveillance information within one month of diagnosis via NETSS or by using the National Bacterial Meningitis and Bacteremia Case Report form (CDC 52.15 Rev 02-93).

Polio

✓ **7.2.13** Report each suspected case of paralytic poliomyelitis to CDC immediately by ☞ telephone.

Rubella

✓ **7.2.14** Report each confirmed case of rubella to CDC promptly by telephone or FAX ☞ and submit supplemental surveillance information within one month of diagnoses via NETSS.

Performance Measure: *Proportion of rubella cases for which the completed case report or NETSS screen were submitted within one month of diagnosis*
Target: *100%*

Tetanus

✓ **7.2.15** Report each case of tetanus to CDC and submit supplemental surveillance ☞ information within one month of diagnosis via NETSS or using tetanus case report form (CDC71.16 Rev 9-96).

Varicella

✓**7.2.16** Report each varicella-related death to CDC using CDC Varicella Death ☞ Investigation Work Sheet.

7.2.17 Report cases of varicella to CDC within one month of diagnosis. See section 7.1.34 for reporting criteria.

7.3 PERINATAL HEPATITIS B SCREENING

For additional details, refer to Chapter 4.3 Perinatal Hepatitis B Prevention

ACTIVITIES to identify HBsAg-pregnant women and prevent perinatal hepatitis B transmission:

✓ **7.3.1** Establish a program-wide system to screen all pregnant women for HBsAg and ensure appropriate prophylactic immunization of their infants and household contacts.

See 7.3.0 ELEMENTS of perinatal hepatitis B prevention program.

7.3.0 ELEMENTS of a perinatal hepatitis B prevention program:

- Maternal HBsAg screening (surveillance)
- Reporting and documentation of screening results
- Case management of infants born to HBsAg-positive mothers
- Follow-up of household contacts

✓ **7.3.2** Assure that prenatal care patients are routinely screened for HBsAg status and procedures for documenting screening results in prenatal care records and hospital medical charts of both mothers and infants are in place and being followed.

Performance Measure: *Percent of pregnant women screened for HBsAg status during current pregnancy*
Target: *At least 90% of all pregnant women.*

✓ **7.3.3** Assure that prenatal care providers, delivery hospitals and laboratories report HBsAg-positive pregnant women to the appropriate health department office.

Performance Measure: *Percent of expected births to HBsAg positive pregnant women reported to the health department.*
Target: *90% of expected births to HBsAg positive pregnant women.*

✓ **7.3.4** Assure that all delivery hospitals and pediatric well care providers report infants born to HBsAg-positive pregnant women to the appropriate health department office.

Performance Measure: *Percent of infants born to HBsAg positive pregnant women reported to health departments*
Target: *At least 90% of expected births to HBsAg positive pregnant women.*

7.3.5 When appropriate, support and assist in the drafting of laws and/or regulations that require prenatal care providers and birthing hospitals to document the HBsAg status of all pregnant women during each pregnancy and laboratories to report HBsAg-positive tests to the health department.

7.4 VACCINE SAFETY

See *Chapter 4 Provider Quality Assurance* and *Chapter 6 Consumer Information* for additional activities related to vaccine safety.

ACTIVITIES to maintain a system to monitor the safety of immunizations:

✓ **7.4.1** Ensure at least one employee is designated with overall responsibility for ☞ vaccine safety and VAERS reporting. Duties should include filling out VAERS forms, promptly reviewing all VAERS reports received, submitting reports to VAERS contractor within seven days of receipt, collecting and forwarding supplemental medical information, answering provider and parent VAERS and vaccine safety inquiries, and fielding communication with and from media.

✓ **7.4.2** Establish/maintain protocols and systems to accept and report adverse events following immunization (VAERS) submitted by public and private health care providers, parents, and vaccinees.

Performance Measure: *Increase in the number of adverse events reported to the immunization program office, by vaccine type and reporting source*
Target: *Set by individual program*

✓ **7.4.3** Review all VAERS reports upon receipt; verify accuracy of key information on form, attempt to complete critical fields, and assign an immunization project number. If all critical information cannot be obtained by the grantee then the report should be forwarded to VAERS if it contains at least the following: a patient identifier (nominal or non-nominal); a vaccine; an adverse event; and an identifiable reporter (of the adverse event)**.**

Performance Measure: *Number and percent of VAERS reports submitted to the contractor within five working days of receipt*
Target: *>90%, set by individual program*

✓ **7.4.4** Routinely obtain supplemental medical information (e.g., autopsy reports, ☞ death certificates, hospital discharge summaries) related to every serious adverse event reported (e.g., death, life-threatening illness, hospitalization, permanent disability).

Performance Measure: *Number and percent of serious adverse event reports for which supplemental medical information was collected*
Target: *> 90% set by individual program*

✓ **7.4.5** Submit supplemental medical information requested by the national VAERS ☞ program within ten working days of receipt of request.

Performance Measure: *Number and percent of requested supplemental reports submitted within ten working days of receipt of request*
Target: *> 90% set by individual program*

ACTIVITIES to ensure that all providers of immunizations report adverse events according to state and/or local public health policies:

✓ **7.4.6** Ensure all local health departments and public health clinics know to report ☞ and report adverse events to the grantee using the VAERS form.

Performance Measure: *Percent of adverse events reported by public clinics for which a VAERS form was received*
Target: *100%*

✓ **7.4.7** Provide all immunization providers (public and private) with a copy of state policies on VAERS reporting, a copy (ies) of the VAERS reporting form, instructions on which adverse events must be or may be reported, and on completing and submitting the form, and updates on VAERS reporting as they arise.

Performance Measure: *Number of newly licensed providers (e.g., pediatricians, family practitioners, general practitioners, clinics) and percent of those provided VAERS and other safety information and training*
Target: *>90% set by individual program*

7.4.8 Encourage providers to submit VAERS reports on adverse events not listed in the National Vaccine Injury Table.

7.4.9 Communicate information on vaccine safety in a timely way to all health care providers, public health officials, state professional associations and the public.

8 Population Assessment

Periodic evaluation of progress toward national, state and local immunization goals enables managers to set objectives, plan strategies and direct limited program resources rationally and effectively. The National Immunization Survey (NIS) provides immunization coverage data on children 19-35 months of age for the state and local immunization grantees and selected urban areas. The Behavioral Risk Factor Surveillance System (BRFSS) provides influenza and Pneumococcal vaccination data for adults age 18 years and older for all 50 states, the District of Columbia and Puerto Rico. Assessment of children entering school and day care provide additional population data points, even though the ultimate purpose of these surveys is to assure compliance with state vaccination laws.

Keywords:
Adult Assessments
Behavioral Risk Factor Surveillance System (BRFSS)
Cluster surveys
Day care assessment
Exemption rates
Immunization coverage data
National Immunization Survey (NIS)
Pockets of need
School assessment
Surrogate measures

Some states have recently added entry requirements for middle/junior high and high school grade levels. If these grades are surveyed, the resulting data may be useful to generate rough estimates of vaccine coverage among adolescents. Nationally, the validity of these estimates will increase as more states add middle school entry requirements.

The NIS, school and day care-based surveys, and BRFSS provide measures of progress toward national Healthy People 2010 immunization goals. Achieving and maintaining 90% coverage of all ACIP-recommended pediatric vaccines by the second birthday remains our highest priority nationally. However, substantial VPD morbidity is occurring in adolescent and adult populations. Therefore, implementing programmatic interventions to increase immunization levels among high risk adolescents and adults is important in order to reach the Healthy People 2010 objectives for these groups.

Independent surveys conducted by state and local public health agencies may be beneficial to confirm the NIS or BRFSS results and to estimate coverage in special sub-populations such as certain racial or ethnic minorities, WIC enrollees, adolescents, health care workers, senior citizens and persons with medical conditions that put them at high risk for VPDs. In addition, programs should identify pockets of under-immunized individuals either by estimating coverage directly or by examining demographic factors known to be associated with under-immunization. Factors such as poverty, large family size and low maternal educational achievement often can be used as surrogates for low immunization coverage.

ACTIVITY AREAS

8.1 General Population Assessments

8.2 Special Population Assessments

References:

- Sampling Procedures for Conducting Immunization Assessments/Validation Surveys for School and Day Care Centers, Retrospective Surveys Using School Systems Databases and Guidelines for Public Health Immunization Clinic Audits for Immunization Project Areas (CDC, 1990) Appendix 2
- Technical Support for Conducting Immunization Assessments/Validation Surveys for Preschool Programs (Daycare, Head Start, and Prekindergarten Programs), Kindergartens, First Grades, And Middle Schools. (CDC, 2003, Appendix # to be provided at a later date).
- National Immunization Survey Reports (CDC)
- Behavioral Risk Factor Surveillance System Reports (CDC)

8.1 GENERAL POPULATION ASSESSMENTS

ACTIVITIES to evaluate progress toward program-wide immunization goals:

- ✓ **8.1.1** Use a CDC-approved sample survey methodology to annually estimate program-wide immunization coverage and exemption rates among children entering kindergarten, first grade, and/ middle school/junior high and validate coverage reports received from schools.
  Note: grantees may submit a data file from annual assessment activities. Upon receipt of the file, CDC will analyze the data and provide the results to the grantees.*

Outcome Measure: *Percent of school enterers who are complete for recommended vaccines.*
Target: *At least 95% of all school enterers*

8.1.2 Using data obtained from the annual school validation assessment, retrospectively estimate immunization coverage of school enterers when they were two years of age. Note: grantees may submit a data file from annual assessment activities. Upon receipt of the file, CDC will analyze the data and provide the results to the grantees.*

Outcome Measure: *Percent of school enterers up-to-date at second birthday.*
Target: *90% of school enterers up-to-date at second birthday*

✓ **8.1.3** Using a CDC-approved sample survey methodology, biennially estimate program-wide immunization coverage and exemption rates of children in programs daycare, Head Start, and prekindergarten programs and validate coverage reports received from these programs. Note: grantees may submit a data file from annual assessment activities. Upon receipt of the file, CDC will analyze the data and provide the results to the grantees.*

Outcome Measure: *Percentage of day care enrollees that are age-appropriately immunized*
Target: *>95%*

✓ **8.1.4** Annually, use the Behavioral Risk Factor Sample Survey (BRFSS) to estimate state-specific influenza and Pneumococcal immunization coverage levels among adults 65 years of age and older, 50-64 (influenza), and 18-64 with high-risk medical conditions.

Outcome Measure: *Influenza and Pneumococcal coverage levels for persons ≥65years of age*

Target: *90%*

Outcome Measure: *Influenza coverage estimates for persons 50-64 years of age and persons aged 18-64 years with asthma, diabetes, or heart disease*
Target: *60%*

Outcome Measure: *Pneumococcal coverage levels for persons 18-64 years with diabetes or heart disease*
Target: 60%

8.1.5 Monitor the impact of varicella immunization on incidence of disease by adding a question about previous infection with varicella disease in the BRFSS.

8.1.6 Using a CDC-approved birth certificate follow-back survey methodology, estimate grantee-wide immunization coverage at the second birthday of children who turn two years of age during a one year period. Note: grantees may submit a data file from annual assessment activities. Upon receipt of the file, CDC will analyze the data and provide the results to the grantees.*

Outcome Measure: *Percent of children up-to-date at the second birthday*
Target: *90%*

*Please note that activities related to school and daycare assessment have changed significantly. Grantees may submit a data file from annual assessment activities rather than submit a summary report. Upon receipt of the file, CDC will analyze the data and provide the results to the grantees. This does not preclude grantees from performing their own analyses, but will reduce the analyses required for grantees' annual reports. Using submitted data, CDC will provide to the grantees:

- Estimates of the percentage of kindergarteners, first graders, and middle/junior high school children who are up-to-date for each of the recommended vaccines;
- Estimates of the percentage of kindergarteners and first graders who were up-to-date for each of the recommended vaccines at their second birthday;
- Estimates of the percentage of children in preschool facilities who are up-to-date for each of the recommended vaccines;
- Estimated coverage rates for preschool, kindergarten, first grade and middle school children by geographic and demographic categories.

8.2 SPECIAL POPULATION ASSESSMENTS

ACTIVITIES to identify and evaluate subpopulations at risk of under immunization and exposure to VPDs:

✓ **8.2.1** Identify and monitor pockets of under immunized children and adults (Pockets of Need {PON's}) using immunization coverage estimates derived from cluster surveys, immunization registries, Medicare billing data, school-enterer and retrospective immunization surveys, provider coverage estimates, long term care facility assessments, and BRFSS enhancements (over sampling specific subpopulations).

Outcome Measure: *Coverage improvement in PONs*
Target: *Set by individual program*

✓ **8.2.2** Assess hepatitis B coverage rates at STD, HIV, adolescent, correctional and other high-risk clinics and facilities.

Performance Measure: *Number [increase] of clinics and facilities serving high risk groups assessed, by facility type*
Target: *Set by individual program*

Outcome Measure: *Estimate hepatitis B coverage by percent of clients offered hepatitis B vaccine who complete the series and type of facility and/or group*
Target: *Set by individual program*

✓ **8.2.3** Assess hepatitis B coverage rates among at-risk immigrant Asian-Pacific populations as appropriate.

Outcome Measure: *Estimate hepatitis B coverage by percent of clients offered hepatitis B vaccine who complete the series and/or population sub-groups*
Target: *Set by individual program*

✓ **8.2.4** Assess coverage rates among WIC, Medicaid and/or SCHIP populations.

Outcome Measure: *Number and percent [increase] of population age-appropriately immunized, by type of program (WIC, Medicaid, SCHIP, etc.)*
Target: *90% up-to-date*

✓ **8.2.5** Determine influenza and Pneumococcal coverage rates among residents and influenza coverage rates among staff of nursing homes and long term care facilities by working with the nursing home licensing agency and other agencies concerned with long term care.

Performance Measure: *Number [increase] of facilities assessed, by facility type*
Target: *Set by individual program*

Outcome Measure: *Estimated percent of resident population in nursing home/long term care facilities immunized in most current influenza season and/or ever immunized with Pneumococcal vaccine*
Target: *90% of all long term care residents*

8.2.6 Use a community-based, household cluster survey to measure immunization coverage and sociological factors associated with failure to immunize. Cluster surveys are resource intensive and should be undertaken only in response to a critical need (e.g., low or persistent drops in other indicators of immunization coverage).

8.2.7 Routinely obtain immunization coverage reports from managed care organizations (Medicaid and commercial) for two-year-olds, 13-year-olds, ≥65-year-olds and/or high risk subpopulations such as persons with diabetes, chronic pulmonary disorders, etc.

Performance Measure: *Number and percent of MCOs routinely providing coverage estimate for various age- and at risk-groups*
Target: *Set by individual programs*

8.2.8 Conduct a survey to determine the number of colleges and universities that require entering students to have MMR2, hepatitis B series, a Td booster, and varicella and/or, where appropriate, meningococcal vaccine.

Performance Measure: *Number and percent of colleges requiring various immunizations for entry*
Target: *Set by individual programs*

8.2.9 Measure influenza vaccination coverage in women who were past 1st trimester of pregnancy during influenza season, using currently pregnant women in BRFSS, managed care databases, or WIC participants; in states participating in the Pregnancy Risk Assessment Monitoring System (PRAMS) (31 states and New York City as of May 2003), work with the local PRAMS coordinator to include standard, CDC-developed influenza vaccination questions on the survey.

Performance Measure: *number of pregnant women offered influenza vaccination; percent of women who were past 1st trimester during influenza season who received influenza vaccination*
Target: *Set by individual programs*

ATTACHMENT 1 – (as of 16 May, 0930hrs)

PANDEMIC INFLUENZA PREPAREDNESS: PLANNING AND IMPLEMENTATION

Influenza viruses are unique in their ability to cause sudden, pervasive infection in all age groups on a global and pandemic scale. Influenza pandemics have occurred three times in the 20th century (1918, 1957, and 1968) with more than 20 million deaths worldwide in the 1918 pandemic alone. Recent avian influenza virus outbreaks infected humans in Asia (1997, 1999, and 2003) and in Europe (2003). If such a virus, in addition to infecting persons, can spread efficiently from person to person, it is clear that it could initiate the next influenza pandemic. It is also clear that State and local jurisdictions will be called on to play critical roles in responding to such an outbreak and as such need to develop and exercise pandemic influenza preparedness and response plans, including surveillance and laboratory capacities.

Pandemic Influenza Preparedness is a public health priority and as such is addressed as a key activity in both the Continuation Guidance for Budget Year Four of the Bioterrorism Cooperative Agreement and the 2004 Immunization Continuation Grant Application Guidance. As State and local health departments move forward on this public health priority the integration of Bioterrorism and immunization planning and program infrastructures are appropriate and necessary. To achieve preparedness and to maximize funding and its efficient and effective use, grantee Immunization and Bioterrorism programs will need to collaborate closely both the development and exercising of jurisdictional pandemic influenza plans.

For the Immunization Program specifically, and also of interest to the grantee's BT Project manager, activity areas to be considered for Pandemic Influenza Preparedness include preparedness planning for those who have not initiated or completed a pandemic influenza plan and preparedness implementation for those who have completed their pandemic influenza plan.

State and local pandemic influenza preparedness plans can be established as a stand-alone plan, an annex to a state's or jurisdiction's "All Hazards" Plan and/or an adjunct to planning for acts of chemical or biological terrorism.

ACTIVITY AREAS

1. Preparedness Planning
2. Preparedness Implementation

References:

- *Pandemic Influenza: A Planning Guide for State and Local Officials* (CDC NVPO) www.cdc.gov/od/nvpo
- Examples of State pandemic influenza preparedness plans (CSTE) www.cste.org
- Continuation Guidance for Budget Year Four of the Bioterrorism Cooperative Agreement
- The 2001 National Pandemic Influenza meeting (an important milestone) and the 2000 archived cybercasts on Pandemic Influenza: www.cdc.gov/nip/flu/news.htm
- Latest updates on influenza activity and reports on current globally circulating novel viruses and influenza outbreaks: www.cdc.gov/ncidod/diseases/flu/fluvirus.htm
- Influenza Pandemic Preparedness Plan. The Role of WHO and Guidelines for National and Regional Planning. Geneva, Switzerland, April 1999 www.who.int/emcdocuments/influenza/whocdscsredc991c.html

PANDEMIC INFLUENZA PREPAREDNESS

The components of a State and local pandemic influenza preparedness planning and implementation include:

1.1 Preparedness Planning

ACTIVITY: prepare a written State/local pandemic influenza preparedness plan:

- Establish an executive planning Committee
- Involve all relevant organizations actively in the public and private sectors in the planning process
- Ensure collaborative network between the public health, bioterrorism and emergency response communities
- Establish relationships, responsibilities, and communication frameworks among various organizations at the national, State and local levels
- Ensure appropriate legal authority in place for dealing with various aspects of the pandemic influenza response
- Focus on actions that are most crucial to effective planning, response and mitigation at the State and local levels, including:
    1. Devise the concept of operations, i.e., the command structure and lines of authority and communication for managing day-to-day activities during the pandemic
    2. Enhance virologic (laboratory-based) and disease-based surveillance systems for influenza
    3. Develop policies and procedures for distributing (and monitoring coverage of) influenza vaccine to the entire population in priority order (depending on vaccine supply)
    4. Develop policies and procedures for providing antiviral agents (amantadine and rimantadine) to high-priority target groups, especially when vaccine is in short supply
    5. Develop a comprehensive communications plan for effective interactions with the media, the medical community, the general public, and neighboring jurisdictions, and to transmit surveillance data and other relevant information to the national level
    6. Develop contingency plans for emergency preparedness, including the provision of adequate medical care and maintenance of essential community services ("human infrastructure")
- "Market" the State and/or local preparedness plan to appropriate partners, stakeholders, lawmakers, and decision-makers to obtain the necessary support and resources in advance of a pandemic influenza declaration

1.2 Preparedness Implementation

ACTIVITY: test and implement a State/local pandemic influenza preparedness plan:

- Exercise the pandemic influenza plan and revise the plan based upon the results of the exercise.